Biodegradable Surgical Solutions
Inion® Clinical and Pre-clinical Evidence Guide

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Inion® Clinical and Pre-clinical Evidence Guide

Introduction

This guide highlights evidence-based pre-clinical and clinical references, in vitro and biomechanical studies as well as literature reviews mentioning the application of Inion® products in published peer reviewed journals, aiming to help health professionals to improve their understanding of clinical outcomes of Inion® products in their work.

The citation information, study designs and clinical outcomes are listed in the table below by product line. Within each product line, clinical evidence is followed by preclinical studies, in vitro tests, biomechanical studies and literature reviews.

COLOUR CODING ACCORDING TO THE PRODUCT LINE:

Inion Hexalon™
Inion Trinion™
Inion FreedomPlate™
Inion OTPS™ Pin
Inion OTPS™ Plating system/ Inion OTPS™ Screw
Inion BioRestore™
Inion S-1™
Inion CPS™ Baby
Inion CPS™

Contents

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion Hexalon™	Weber et al. (2015) Tibial and Femoral Tunnel Changes After ACL Reconstruction The American Journal of Sports Medicine. 2015; Vol. 43, No. 5	Clinical study: Arthroscopic ACL reconstruction with the same surgeon, surgical technique, and rehabilitation protocol	Inion Hexalon™ screw	ACL reconstruction	18 patients	2 years	Both tibial and femoral tunnels are dynamic, with tunnel expansion and contraction over time. At both the tibial and femoral tunnels, the aperture and midsection cross section areas generally increased to the 24th postoperative week, eventually plateauing before decreasing in area from 1 year to final follow-up at 2 years. The screws used in the current study have been used as the only fixation method in a previous study without screw related adverse outcomes. In the current study, none of the patients had MRI findings suggestive of a reaction to the bioabsorbable screw fixation.
Inion Hexalon™	Kiekara et al. (2017) Femoral and Tibial Tunnel Diameter and Bioabsorbable Screw Findings After Double-Bundle ACL Reconstruction in 5-Year Clinical and MRI Follow-up The Orthopaedic Journal of Sports Medicine. 2017; 5(2), 2325967116685525	Clinical study: To evaluate the ossification pattern of the tunnels, the communication of the 2 femoral and 2 tibial tunnels, and screw absorption findings in MRI	Inion Hexalon™ screw	ACL reconstruction	31 patients	5 years	Tunnel enlargement was followed by tunnel narrowing in 5-year follow-up after double-bundle ACLR. Tunnel communication and tunnel cysts were frequent MRI findings and not associated with adverse clinical evaluation results. At the 2-year MRI, all tunnels were enlarged, with no signs of ossification. At the 5-year MRI, 44% of the tunnels were evenly narrowed, 48% were conical, and 8% were fully ossified.
Inion Hexalon™	Järvelä et al. (2017) Järvelä S, Kiekara T, Suomalainen P, Järvelä T: Double-bundle versus single-bundle anterior cruciate ligament reconstruction: A prospective randomized study with 10-year results The American Journal of Sports Medicine. 2017; 45(11):2578-2585	Clinical study: The double-bundle ACL reconstruction resulted in significantly fewer graft failures and subsequent revision ACL surgery than the single-bundle surgeries during the 10-year follow-up	Double-bundle (DB): Inion Hexalon™ screw Single-bundle (SBB): Inion Hexalon™ screw Single-bundle (SBM): Titanium interference screw	ACL reconstruction	70 patients (DB 24, SBB 23, SBM 23)	10 years	1 No reported adverse reactions with patients fixed using Inion Hexalon™ screws 2. No reported fixation failures due to screws, their degradation profile or materials

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Inion Hexalon™	Järvelä et al. (2016) Järvelä S, Kiekara T, Järvelä T: Double-bundle versus single-bundle anterior cruciate ligament reconstruction: A prospective randomized study with 10-year results The ACL study group 2016 Åre Meeting, Åre, Sweden, March 13-17, 2016; and The star paper session of the 17th ESSKA congress, Barcelona, Spain, May 4-7, 2016	Clinical study: The double-bundle ACL reconstruction resulted in significantly fewer graft failures and subsequent revision ACL surgery than the single-bundle surgeries during the 10-year follow-up	Double-bundle (DB): Inion Hexalon™ screw Single-bundle (SBB): Inion Hexalon™ screw Single-bundle (SBM): Titanium interference screw	ACL reconstruction	70 patients (DB 24, SBB 23, SBM 23)	10 years	1. No reported adverse reactions with patients fixed using Inion Hexalon™ screws 2. No reported fixation failures due to screws, their degradation profile or materials
Inion Hexalon™	Kiekara et al. (2014) Tunnel communication and increased graft signal intensity on magnetic resonance imaging of double-bundle anterior cruciate ligament reconstruction Arthroscopy: The journal of arthroscopic and related surgery 2014; 30 (12): 1595-1601	Clinical study: To evaluate the association between MRI findings of tunnel communication and increased graft signal intensity and clinical evaluation of knee stability and outcome after double bundle ACL reconstruction	Double Bundle (DB) Inion Hexalon™ screw	ACL reconstruction	74 patients (Analysis for 59 patients: 42 male and 17 female patients, 40 right and 19 left operated knee, mean age of 35 years)	2 years	1. The MRI findings of tunnel communication or increased graft SI did not cause knee laxity 2 years after DB ACL reconstruction 2. Tibial tunnel communication was associated with increased range of movement with flexion, and increased AM graft SI was associated with reduced range of flexion in the knee 3. At 2-year follow-up, 59% of patients had returned to sports pre-injury activity level and 34% at a lower activity level while 7% of them could not return to sports
Inion Hexalon™	Suomalainen et al. (2014) Effect of tunnel placements on clinical and magnetic resonance imaging findings 2 years after anterior cruciate ligament reconstruction using the double-bundle technique J. Sports Med. 2014; 5:197-203	Clinical study: To evaluate the association between the clinical and magnetic resonance imaging finds of a reconstructed ACL	Double Bundle (DB) Inion Hexalon™ screw	ACL reconstruction	75 patients (DB)	2 years	1. The clinical measurements and knee scores were all significantly better at the 2-year follow-up than preoperatively 2. No association between graft visibility and the 2-year clinical status of the knees in either

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Inion Hexalon™	Suomalainen et al. (2012) Double-bundle versus single-bundle anterior cruciate ligament reconstruction - a prospective randomized study with 5-year results Am J Sports Med 2012; 40:1511	Clinical study: Double-bundle ACL reconstruction with hamstring autografts and aperture screw fixation has fewer graft ruptures and rates of osteoarthritis and better stability than single-bundle reconstruction	Double-bundle (DB): Inion Hexalon™ screw Single-bundle (SBB): Inion Hexalon™ screw Single-bundle (SBM): Titanium interference screw	ACL reconstruction	65 patients (DB 20, SBB 21, SBM 24)	5 years	1. No reported adverse reactions with patients fixed using Inion Hexalon™ screws 2. No reported fixation failures due to screws, their degradation profile or materials
Inion Hexalon™	Järvelä et al. (2008a) Double-bundle anterior cruciate ligament reconstruction using hamstring autografts and bioabsorbable interference screw fixation – a prospective, randomized, clinical study with 2-year results Am J Sports Med 2008; 36:290	Clinical study: Rotational stability of the knee is better when using a double-bundle technique instead of a single-bundle technique for an anterior cruciate ligament reconstruction	Double-bundle (DB): Inion Hexalon™ screw Single-bundle (SBB): Inion Hexalon™ screw Single-bundle (SBM): Titanium interference screw	ACL reconstruction	63 patients (DB 22, SBB 21, SBM 20)	2 years	1. Inion Hexalon™ screws were soft already 8 months after surgery, totally absorbed at 18 months with 10 patients who had revision surgery 2. No screw removal on revision surgery, new tunnel was created just drilling through previously inserted Inion Hexalon™ screw 3. None of the patients had any adverse reactions from Inion Hexalon™ screws
Inion Hexalon™	Järvelä et al. (2008b) Book: The anterior cruciate ligament: reconstruction and basic science. Chapter: Improving biodegradable interference screw properties by combining polymers 2008 Saunders	Clinical study: Prospective, randomized, clinical trial using either biodegradable screw or metallic screw	ACL reconstruction using either Inion Hexalon™ screw or Titanium interference screw	ACL reconstruction	49 patients (26 Inion Hexalon™, 23 titanium interference screw)	1 year MRI follow-up 27 months	1. Inion Hexalon™ screws were soft 8 months after surgery, almost totally absorbed at 18 months and totally absorbed after 2 years 2. On revision surgery, new tunnel was created just drilling through previously inserted screw 3. No clinically significant inflammatory, foreign body, or other adverse tissue reactions noticed 4. MRI examination revealed that Inion Hexalon™ screws were totally absorbed within the follow-up

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Inion Hexalon™	Järvelä et al. (2008b) Book: The anterior cruciate ligament: Reconstruction and basic science. Chapter5: Improving biodegradable interference screw properties by combining polymers 2008 Saunders	Biomechanical study: A three-part test to study the fixation strength of Inion Hexalon ™ screw and to evaluate its suitability for ACL reconstruction	Soft tissue graft fixation comparison: Inion Hexalon™ vs. conventional metal screw (1) and another biodegradable interference screw (2) Bone-tendon-bone graft fixation comparison: Inion Hexalon™ vs. another biodegradable interference screw (3) Torsional strength comparison (4) _____ Strength retention *in-vitro*.	Fresh skeletally mature porcine cadaver specimens. _____ Phosphate buffer solution	(1) N=13 (2) N=8 (3) N=8 (4) N=6 _____ N=4/each time point	- - - - _____ *In vitro* study up to 12 weeks	Inion Hexalon™ screw provides: 1. Similar initial fixation strength when compared to other biodegradable and conventional metal interference screws 2. Higher torsional strength when compared to other commercially available biodegradable interference screws 3. 80% of the initial mechanical strength can be maintained as long as 12 weeks in vitro
Inion Trinion™	Järvelä et al. (2010) All-inside meniscal repair with bioabsorbable meniscal screws or with bioabsorbable meniscus arrows-a prospective, randomized clinical study with 2-year results Am J Sports Med, 2010; 38, 11: 2211-2217	Clinical study: The comparison of clinical outcomes with a 2-year follow-up between bioabsorbable meniscal screw (Inion) and bioabsorbable meniscus arrow (ConMed)	Inion Trinion™	Meniscus Repair	42 patients (21 Inion Trinion™ screws, 21 arrows)	2 years	1. 17% failures were observed in the screw group and 30% in the arrow group 2. No chondral damage of the femoral condyles was observed in the patients with screws in the healing process while 6 patients with meniscus arrows had such chondral damage

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Inion FreedomPlate™	Edmonds (2012) Use of an absorbable plate in the management of a clavicle fracture in an adolescent Am J Orthop. 2012;41(1):29-32	A case report & Literature review	Inion FreedomPlate™ 100 mm concave fixed with 6 Inion OTPS™ 2.8 mm screws	Delayed (14 weeks after injury) clavicle fracture fixation	N=1	18 months	1. After 18 months of follow-up, physical examination revealed full active shoulder ROM and a well-healed incision with no evidence of erythema or underlying reaction to the implant, no apparent complications specific to the implant 2. Amount of subcutaneous irritation seems to be insignificant 3. After 18 months, the plate edges were not discernible, but remnant plate was palpable under the skin 4. Inion FreedomPlate™ can be easily contoured to the relatively irregularly S-shaped clavicle 5. Low profile construct with cut-off screw heads and no need for second surgery and implant removal
Inion FreedomPlate™	Noh et al. (2012) Outcomes of operative treatment of unstable ankle fractures: a comparison of metallic and biodegradable implants J Bone Joint Surg Am. 2012;94e166(1-7)	Clinical study	Inion FreedomPlate™ and Inion OTPS™ screws (3.1 mm, 4.5 mm LAG and fully threaded)	Unilateral ankle fractures: biomalleolar and trimalleolar fractures, a lateral malleolar fracture, or an isolated medial malleolar fracture with displacement of ≥2 mm. Syndesmosis stabilization performed if tibiofibular clear space widening was ≥2 mm.	102 (metal 53, biodegrad-able 49)	12 months	1. Fixation results of unstable ankle fractures using biodegradable plate and screws or metallic implants were comparable (except AOFAS scale scores) 2. Comparable outcomes of isolated lateral malleolar fractures with or without syndesmosis injury fixed using biodegradable or metallic products 3. In metallic group, 18 of 53 had hardware removal surgery during the first year after the index surgery 4. No osteolysis or swelling reported on biodegradable group; 8 of 49 reported sensation of a prominence under the skin and 4 of reported 8 had mild tenderness 5. Due to degradation of biodegradable implants, stress shifts to bone, which prevents bone resorption and with metallic implants noticed stressconcentration can be avoided

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion FreedomPlate™	Yang et al. (2019) Lateral wall osteotomy combined with embedded biodegradable implants for displaced intra-articular calcaneal fractures Journal of Orthopedic Surgery and Research 2019; 14:74	Clinical study	Inion FreedomPlate™ and Inion OTPS™ screws (3.1 mm, fully threaded)	Calcaneal fractures (Sander's type II, III and IV) with osteotomy of lateral wall, gap between fractures > 3 mm and/or step-off > 2 mm	17 patients (19 fractures)	34 months, range 28 to 48 months	1. To reduce wound complications after extensile lateral approach (ELA), a new technique of lateral wall osteotomy combined with embedded biodegradable plate and screws 2. Plaster cast was applied for 4-6 weeks postoperatively. After 8-10 weeks partial weight-bearing with crutches was allowed 3. No nonunion, delayed union, or malunion was observed after a mean follow-up period of 34.69 +/-5.22 months 4. No soft tissue reactions was found in all feet at the final follow-up 5. According to the findings of this study, the indications of this approach were Sander's type II and III closed calcaneal fractures
Inion FreedomPlate™	Vaananen et al. (2009) Fixation properties of a biodegradable "free-form" osteosynthesis plate with screws with cut-off screw heads: Biomechanical evaluation over 26 weeks Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology 2009: No4, Vol.107	Biomechanical study: Comparison of the postoperative fixation properties of a biodegradable osteosynthesis "free-form" plate achieved with countersunk screws vs. fixation provided by screws with cut-off screw heads	Inion FreedomPlate™ fixed using Inion OTPS™ screws (2.0x10mm)	Sawbones in phosphate buffer solution	N=5/each time point/ each test type	*In vitro* study up to 26 weeks	1. Screws with cut-off screw heads provide postoperative fixation strength of the osteosynthesis free-form plate equivalent to that provided by conventional countersunk screws during 26 weeks of hydrolytic degradation 2. The strength retention rate appeared to be adequate for a normal fracture healing period with both studied fixation techniques 3. Major failure mode (=screw shaft breakage) indicates that screw-plate interlock is not the weakest point of the fixation even with screws with cut-off screw head
Inion OTPS™ Pin	Chukwunyerenwa et al. (2012) Use of bioabsorbable pin in innominate osteotomy for correction of developmental dysplasia of the hip J.Bone Joint Surg BR 2012 vol.94-B, 148	Clinical study	Inion OTPS™ Pin	Innominate osteotomy - treatment of developmental dysplasia of the hip (DDH)	120 cases	15 months	1. There was no foreign body reaction 2. Mean acetabular index of 18.7° at latest follow-up with no loss of correction 3. The use of bioabsorbable pins eliminates the need for second anaesthetic to remove pins with significant cost benefit without compromising outcome

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Inion OTPS™ Pin	Chotel et al. (2011) Knee osteochondral fractures in skeletally immature patients: French multicenter study Orthopaedics & Traumatology: Surgery & Research (2011) 97, S154-S159	Clinical study: Retrospective multicenter study to investigate the characteristics and to analyze the results of repositioning osteochondral fractures in skeletally immature patients	Inion OTPS™ Pin	Femoral and patellar osteochondral fractures. (In 9 cases lateral femoral condyle, in 5 cases patella) Screw fixation, pin fixation, suture fixation, biological glue	Screw fixation (n=5), resorbable pins (n=5), pull-out suture (n=4), +6 patients also received biological glue.	30 months	1. No postoperative complications were observed, no revision for osteochondral fragment repositioning failure 2. With 5 patients it was documented with MRI that all the fractures seemed to have achieved union at the final examination (30 months) 3. Secondary patellar stabilization surgery (n=3) was performed later because of discomfort related to new episodes of instability 4. The main advantage of resorbable implant fixation is the absence of second operation to remove the material
Inion OTPS™ Pin	Penton and Cascio (2008) Internal fixation of osteochondritis dissecans in the Knee Operative Techniques in Sport Medicine 16:97-101	Literature review of options for internal fixation of osteochondritis dissecans	Inion OTPS™ Pin	Osteochondritis dissecans lesions	-	-	1. New evidence supports the use of bioabsorbable pins and screws as fixation devices in the treatments of OCD lesions 2. Larsen et al used bioabsorbable screws to achieve healing of an OCD lesion in 6 of 7 patients 3. Pull-out and shear loads of the bioabsorbable screws show to provide adequate stability for healing
Inion OTPS™ Pin	Rocher (2007) A report of 89 hallux valgus cases with 356 Inion OTPS™ Biodegradable Pins	Unpublished case report: Comparison of biodegradable pins and metallic K-wires in hallux valgus treatment	Inion OTPS™ biodegradable pins (356 pins in total)	Hallux valgus cases of types I, II and III	89 biodegrad-able pin operations (356 pins in total)	9 months	1. All osteotomies healed well 2. There were no non-unions, allergic reactions or tissue reactions
Inion OTPS™ Pin	Mavrogenis et al. (2009) Early Experience with Biodegradable Implants in Pediatric Patients Clin Orthop Relat Res (2009) 467:1591–1598	Clinical study	Inion OTPS™ Pin	Congenital malformations, large reconstruction after tumor excision, fractures and osteotomies of the upper extremity, and hand trauma with bone and soft tissue defects	52 pcs of Inion OTPS™ Pin were implanted.	Mean 17 months, range 7–22 months	1. At a minimum follow up of 7 months (mean, 17 months; range, 7–22 months), wound healing was uncomplicated; local or systemic inflammatory tissue reactions, foreign body reactions, and infections were not observed. Bone healing was complete. 2. Biodegradable copolymers of poly-L-lactic-poly-DL-lactic acid and trimethylene carbonate can be used safely and effectively for reconstruction and fixation of bone in children and adolescents.

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Inion OTPS™ Pin	Dawson et al. (2014) Bioabsorbable pins for bone fixation in the less invasive innominate osteotomy J Pediatr Orthop B. 2014 Sep;23(5):426-9	Clinical study	Inion OTPS™ Pin	Less invasive innominate osteotomy for persistent or delayed diagnosis DDH	A total of 80 hips from 70 patients	4–6 years	1. The use of bioabsorbable pins in this instance is as effective and safe as metal fixation for securing the bone graft 2. No postoperative complications were reported 3. The increased unit cost of the implant over the threaded K wires is offset by the need to remove through reoperation the K wire fixation
Inion OTPS™ Plating system	Gaiarsa et al. (2015) Comparative study between osteosynthesis in conventional and bioabsorbable implants in ankle fractures Acta Ortop Braa. 2015; 23 (5): 263-267	Clinical study: Comparison of biodegradable and metallic plates/screws in ankle fracture treatment	Inion OTPS™ ankle plates/screws	Uni- or bimalleolar ankle fractures classified as Weber B or C	20 patients (19 for follow-up: 10 in absorbable group and 9 in metal group)	9 months	1. The clinical outcomes identified by functional AOFAS score were similar in metal and absorbable groups 2. The radiographic outcome, measured by loss of reduction was similar in both groups 3. Higher rate of secondary surgery for implant removal were undertaken in the metal group 4. The surgical time in ankle osteosynthesis with absorbable material appears to be greater than when using metallic material, but not statistically significant
Inion OTPS™ Plating system	Kukk and Nurmi (2009) A retrospective follow-up of ankle fracture patients treated with a biodegradable plate and screws Foot Ankle Surg. 2009;15(4): 192-7	Clinical study: Retrospectively follow-up of ankle fracture patients treated with a biodegradable plate and screws, and to evaluate the clinical outcome and occurrence of complications	Inion OTPS™ 8-hole plate, Inion OTPS™ screws (2.8mm, 3.1mm, 4.5mm fully threaded and cannulated) and Inion OTPS™ 2.0mm pins	Lateral malleolar fractures Bimalleolar fractures Syndesmosis ruptures	50 patients (36 lateral malleolar, 2 with syndesmosis rupture + 14 bimalleolar fractures, 3 with syndesmosis rupture)	17 months	1. No perioperative complications occurred and all fractures healed well 2. Fracture lines were classified as anatomical in 49 patients and good in 1 case 3. Postoperative complications with 8 patients. The plate was observed to have degraded by 18 months, but some screw head remnants were identified inside granulomatous tissue in 4 cases 4. Studied biodegradable implants yielded fracture healing and functional results comparable to those previously reported after conventional metal fixation

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Inion OTPS™ Plating system	Andreassen et al. (2008) Healing of ankle fractures: Comparison of biodegradable and metal plate and screws (Manuscript for the podium presentation no 504, AAOS 2008 Annual Meeting)	Clinical study: Prospective, double-blinded, randomized, multi-center investigation	Inion OTPS™ Ankle plate and Inion OTPS™ screws	31 isolated, unstable lateral malleolar fractures, 9 bi- or trimalleolar fractures	40 patients (20 metal system, 20 biode-gradable system)	12 months	1. Successful radiological fracture healing was achieved in 37 patients (18 biodegradable and 19 metal groups) at 12 months 2. 1 fixation failure in biodegradable group due to full weight bearing too early postoperatively 3. The biodegradable plate provided qualitatively similar fracture healing results as the metal plate 4. At 12 months, 1 patient in biodegradable and 7 in metal group expressed desire for device removal 5. The safety profiles were similar in both groups
Inion OTPS™ Mesh	Campbell et al. (2009) Surgical Stabilization of Rib Fractures Using Inion OTPS Wraps—Techniques and Quality of Life Follow-Up The Journal of TRAUMA - Injury, Infection, and Critical Care; 2009; Volume 67, Number 3, September 2009	Clinical study: Acute surgical fixation of fractured ribs	Inion OTPS™ Mesh plates and Inion OTPS™ Screws	Open reduction and internal fixation of traumatic fractured ribs	32 patients, mean age 53 years, 20 patients in 2.8 years follow-up	6 weeks / 2.8 years (1039 days)	All patients were satisfied with the results of the operation. The patients who underwent rib fixation felt more content with the operated ribs and found them to be causing less pain than the non-operated ribs. All patients claimed they would recommend having ribs surgically stabilized. A single patient experienced nonunion of the fixed rib. Redo operation using the same technique resulted in successful healing.
Inion OTPS™ Mesh	Väänänen et al. (2010) The use of a biodegradable mesh plate to augment grafting of an acetabular defect J Bone Joint Surg [Br] 2010;92-B:179-85	Laboratory investigation and clinical pilot study	Inion OTPS™ Mesh plates and Inion OTPS™ 3.1 mm screws	Augment grafting of an acetabular defect at total hip replacement	6 patients	19–50 months	1. All the patients had a satisfactory outcome and no mechanical failures or other complications were observed. 2. No primary or late infections occurred 3. No protrusion of the impacted graft was observed beyond the mesh plate 4. The mesh plate was easy to shape, left no sharp edges, and could tolerate the force transferred in the impaction grafting similarly to a metal mesh

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Inion OTPS™ Screws	Kurikka et al. (2006) Syndesmosis fixation in the osteosynthesis of ankle injury at Turku University Central Hospital (TYKS) Article translation - Original publication in Finnish in Suomen Ortopedia ja Traumatologia 2006; 29:236-238	Clinical study: Biodegradable screws compared with metal screws - a retrospective study	Inion OTPS™ 4.5 mm syndesmosis screw	Syndesmosis rupture	700 patients (257 metallic screws, 443 bio-degradable screws)	3–4 months	1. All metal screws were removed 6 to 8 weeks after the operation 2. Biodegradable screws offer a significant benefit in the fixation of syndesmosis injuries when compared with metallic screws as there is no need for the surgical removal of the screw 3. When inserted correctly, biodegradable syndesmosis screw provides stability for a distal tibiofibular joint similar to that when using a conventional metallic screw 4. Biodegradable screw does not increase the risk of infection
Inion OTPS™ Screws	Poircuitte et al (2015) Resorbable osteosynthetic devices in pediatric traumatology: a prospective series of 24 cases Eur J Orthop Surg Traumatol 2015; 25:997-1004	Clinical study: Use of the biodegradable screws in pediatric surgery	Inion OTPS™ 2.8 mm screw	Tibial spine fractures, osteochondritis dissecans of distal femur, fractures of medial epicondyle of distal humerus, distal tibial apophyseal fractures	24 patients Average age 12.5 years (47 screws were used)	Average 10 months Maximum 2 years	1. Similar outcomes to traditional techniques in terms of functional properties and bone healing 2. Radiographic follow-up revealed no secondary displacement, and all of the fractures had healed 3. No subjective or objective instability could be detected by clinical examination 4. No osteolysis was seen around the screws 5. No growth disturbance were notices
Inion BioRestore™	Tirkkonen et al. (2013) Osteogenic medium is superior to growth factors in differentiation of human adipose stem cells towards bone forming cells in 3D culture European Cells and Materials 2013; 25: 144-158	*In vitro* study: Study of osteogenic medium and growth factors in differentiation of human adipose stem cells towards bone-forming cells in 3D culture	Inion BioRestore™	-	-	-	1. Inion BioRestore™ with osteogenic medium was superior to growth factors in differentiation of human adipose stem cells towards bone-forming cells *in vitro*.
Inion BioRestore™	Clozza et al. (2012) Three-dimensional evaluation of bone changes following ridge preservation procedures Int J Oral Maxillofac Implants. 2012 ;27(4):770-5	Clinical study: The alveolar ridge changes in three dimensions following tooth extraction and a ridge preservation procedures (RPP) with Inion BioRestore™	Inion BioRestore™	Teeth extractions	13 patients (32 teeth)	1 week to 3 months	1. Less clinical loss in width than in height indicates that intrasocket grafting with bioactive glass was better able to counteract the reduction in alveolar width than the buccal and oral wall height loss

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Inion BioRestore™	Haimi et al. (2009) Calcium phosphate surface treatment of bioactive glass causes a delay in early osteogenic differentiation of adipose stem cells (ASCs) J Biomed Mater Res A. 2009; 91(2):540-7	*In vitro* study: The effect of three-dimensional bioactive glass scaffolds with and without Ca-P treatment on the attachment, proliferation, and osteogenic differentiation of ASCs	Inion BioRestore™	-	-	-	1. ASCs cultured on non-treated Inion BioRestore™ scaffolds showed significantly higher ALP activity than Ca-P surface treated scaffolds 2. ASCs combined with 3D bioactive glass Inion BioRestore™ scaffolds have potential in those clinical applications where both osteoconductive and osteostimulative properties are required
Inion BioRestore™	Moimas et al. (2006) Rabbit pilot study on the resorbability of three-dimensional bioactive glass fibre scaffolds ActaBiomaterialia 2006; 2:191–199	Preclinical study: The study of the resorption process and the feasibility of using 3D porous bioglass scaffold as bone filler in rabbit tibia	Inion BioRestore™	-	30 Rabbits (female)	6 months	1. 3D bioglass scaffolds and morsels did not give rise to inflammatory phenomena in the bone tissue 2. 3D bioglass scaffolds and morsels with 55-60% porosity are osteoconductive and effective in helping new bone formation and remodelling 3. Filling using the 3D constructs aided trabecular bone formation also in areas in which bone was not naturally present 4. 3D bioglass scaffolds and morsels can be resorbed and replaced by new bone within 6 month in vivo
Inion BioRestore™	Moimas (2006) In situ Tissue Engineering, effect of a porous bioactive glass scaffold on bone healing: in vivo rabbit study 10th Meeting and Seminar on: Ceramics, Cells and Tissues - Materials for Tissue Engineering, Chemistry and Microstructure: The Role for Ceramics; Faenza, Italy, 2006, ISTEC-CNR-Faenza; Published by ConsiglioNazionaleDelleRicerch ep.247-254	Preclinical study: The evaluation of osteo-conductivity, overall effect on the osteogenetic process and degradation process of both 3D bioactive glass fibres and Novabone	Inion BioRestore™	-	30 Rabbits (female)	6–26 weeks	1. 3D porous scaffold made out of bioactive glass fibres resulted positive features with respect to material degradation, osteoconductivity, effect on the restitutioadintegrum of a bone defect, and therefore represent a successful alternative to commercially available products such as Novabone

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Inion BioRestore™	Inion data on file testing report T211R239/2016(2016) Antibacterial effect of bioactive glass 0608TTU agaist staphylococcus aureus ssp. Aureus ATCC BAA-44, Staphylococcus aureus ATCC 49230 and Staphylococcus epidermidis ATCC 51625 Biosafe- Biological Safety Solutions Ltd., Kuopio, Finland; May 2016	*In vitro* study	Inion BioRestore™	-	-	-	1. The study demonstrates that Inion BioRestore™ has antibacterial properties
Inion S-1™	Chen et al. (2016) Outcome observed during 1-year clinical and radiographic follow-up of patients treated for 1- or 2-level cervical degenerative disease using a biodegradable anterior cervical plate J Neurosurg Spine 2016; 25: 205–212	Clinical study: The comparison of clinical results after ACDF treated with bioresorbable versus titanium plates	Inion S-1™ Plating system	Cervical spinal degenerative disease (including 31 patients and 38 segments, C3-C4, C5-C6)	31 patients	1 year	1. The relatively comparable early clinical and radiographic outcomes and the overall acceptable complication rates for bACP and mACP use suggest that bACPs could be used as alternative instruments in ACDF 2. At 3 months postoperatively, the mean mJOA and VAS scores had significantly ($p < 0.05$) improved to satisfactory levels in both groups. Moreover, at the latest follow-up, clinical symptom relief was observed as well 3. No screw or plate breakage was observed during insertion, nor did any patients experience cerebrospinal fluid leakage or postoperative emergent tracheotomy
Inion S-1™	Rodrigo et al. (2015) Long-term follow-up of anterior cervical discectomy and fusion with bioabsorbable plates and screws Clinical Neurology and Neurosurgery 2015; 136: 116–121	Clinical study: The long term effectiveness of Inion S-1™ in use with the anterior cervical discectomy and fusion for treating the cervical spinal degenerative disease	Inion S-1™ Plating system	Cervical spinal degenerative disease (including 13 one-level and 4 two-level patients, most common level C5-C6)	17 patients	5–7 years	1. None had associated complications such as edema in adjacent tissues or long-term infections 2. All segments have documented fusion 3. No patient had to be re-operated due to failure or migration of the materials used in surgery 4. Easy handling of resorbable plate and good tolerance of materials 5. Degradable materials offer an alternative to classical ACDF with titanium plates

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion S-1™	Nabhan et al. (2009) Comparison of bioresorbable and titanium plates in cervical spinal fusion – early radiologic and clinical results J Spine Disord Tech 2009; 22: 155-161	Clinical study: Comparison of clinical results, segmental motility, magnetic resonance imaging compatibility and change of the bone density of a cervical spine segment treated with either bioresorbable or titanium plate	Inion S-1™ Plating system	Symptomatic degenerative disc disease with radiculopathy	37 patients (19 in resorbable group, 18 in metal group)	6 months	1. Anterior plate fixation with bioresorbable plate has the same fusion progress and stability as titanium 2. No complications like soft tissue swelling and infection occurred
Inion S-1™	Nabhan et al. (2008) Comparison of bioresorbable and titanium plates in cervical spinal fusion Abstract, The Spine Journal 2008; 8:1S-191S	Clinical study: The comparison of clinical results, segmental motility, magnetic resonance imaging compatibility and change of the bone density of a cervical spine segment treated with bioresorbable versus titanium plates	Inion S-1™ Plating system	One-level cervical radiculopathy	37 Patient (19 patients in resorba-ble group, 18 patients in metal group)	12 months	1. Anterior plate fixation by using bioresorbable plate has the same fusion progress and stability as Titanium 2. During the study, no complications like soft tissue swelling and infection occurred
Inion S-1™	Tomasino et al. (2009) Bioabsorbable instrumentation for single-level cervical degenerative disc disease: a radiological and clinical outcome study Journal of Neurosurgery: Spine, November 2009 ;11(5):529-537	Clinical study: The feasibility and radiological and clinical outcomes of the bioabsorbable plates for Anterior Cervical Discectomy and Fusion	Inion S-1™ Plating system	Cervical radiculopathy spondylosis or myelopathy	30 patients	6 weeks to 12 months	1. Absorbable instrumentation provides better stability than the absence of a plate 2. No device-related complications, hardware failure and adverse tissue reaction caused by the implant 3. The fusion rate and outcome are comparable to the results achieved with metallic plates
Inion S-1™	Franco et al. (2007) Use of resorbable implants for symptomatic cervical spondylosis: experience on 16 consecutive patients J Neurosurg Sci 2007;51:169-75	Clinical study: The clinical results of anterior cervical discectomy and fusion with and without bioresorbable plates	Inion S-1™ Plating system	Degenerative cervical spondylosis	29 patients (16 with plates and 13 without plates)	12–15 months	1. Increased stability and fusion rate when a cervical plate was used 2. No interference with the postoperative neuro-radiological images 3. Continuous load transferring from resorbable plates to the graft and osteoligmentous spine during resorption

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Inion S-1™	Freeman et al. (2006) In vitro comparison of bioresorbable and titanium anterior cervical plates in the immediate postoperative condition J Spinal Disord Tech 2006;19:577–583	Biomechanical study: The comparison of stabilization and load sharing between bioresorbable plates and titanium plating	Inion S-1™ Plating system	-	16 fresh frozen human cervical motion segments	-	1. Greater load sharing through the graft and osteoligamentous spine in bioresorbable group than in titanium group 2. Well contoured bioresorbable plates can perform their graft containment function by providing significant stability to the fusion construct while undergoing simulated loading 3. No plate failures or graft migration
Inion CPS™ Baby	Salokorpi et al. (2015) Frontal cranial modelling using endocranial resorbable plate fixation in 27 consecutive plagiocephaly and trigonocephaly patients Childs Nerv Syst. 2015; 31(7): 1121-1128	Clinical study: The evaluation of endocranial resorbable plate fixation and its clinical and radiographic results in frontal remodelling cranioplasty for plagiocephaly and trigonocephaly patients with follow-up sufficiently long for plates to have been completely resorbed	Inion CPS™ Baby 1.5 mm Plating system	Plagiocephaly and trigonocephaly	27 patients with age ranged from 7.6 to 55.2 months	50.6 months of mean follow-up for aesthetic results 79.17 months of mean follow-up for complications	1. With long term follow-up, it is found that placement of resorbable plates on the inner surface of cranium is safe, stable, and results in satisfactory aesthetics without interfering with the ossification of the cranial bones
Inion CPS™ Baby	Nam et al. (2011) Distraction osteogenesis with pivot plate in the treatment of scaphocephaly J Craniofac Surg 2011; 22: 96-99	Clinical study: The feasibility of distraction osteogenesis with a pivot plate for scaphocephaly	Inion CPS™ Baby 1.5 mm Plating system	Craniosynostosis: scaphocephaly	3 children	16–24 months	1. Advantages of using 2 distraction devices with absorbable plates: no need of a strip osteotomy after the bilateral temporoparietal osteotomy; aesthetic appearance (a more symmetric and satisfactory cranium form) 2. No relapse or inhibition of growth and bone defect was well healed
Inion CPS™ Baby	Hormozi et al. (2011) Surgical treatment of metopic synostosis Craniofac Surg 2011;22: 261-265	Clinical study: The clinical outcomes of Inion CPS™ Plating system combined with a new surgical technique	Inion CPS™ Baby 1.5 mm Plating system (5-hole plate and 20-hole plate)	Metopic synostosis	60 children	5 years	1. Lower complication rate with new surgical technique and absorbable plates than with metal plates 2. Using absorbable implants hardware removal can be avoided decreasing the revision rate

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Inion CPS™ Baby	Serlo et al. (2007) Effective correction of frontal cranial deformities using bio-degradable fixation on the inner surface of the cranial bones during infancy Childs NervSyst 2007; 23:1439–1445	Clinical study: The use of resorbable fixation devices on the inner orendocranial aspect of the cranium	Inion CPS™ Baby 1.5 mm Plating system	Craniosynostosis: trigonocephaly; plagiocephaly; brachycephaly	10 children with age range from 7–35 months	0.5–6 years	1. The use of resorbable fixation devices on the inner or endocranial aspect of the cranium provided a satisfactory cosmetic result 2. No wound infection and delayed union 3. Seven out of ten cases were judged as excellent and three as good, none as fair or poor
Inion CPS™ Baby	Iatrou et al. (2006) The use of biodegradable plates in oral and maxillofacial surgery in children XVIIIth Congress of the European Association for Cranio-Maxillofacial Surgery, Barcelona, Spain, September 12-15, 2006, and published in the Journal of Cranio-Maxillofacial Surgery 34 (Suppl. 1): 67, 2006	Clinical study: The efficacy and importance of using biodegradable plates in children	Inion CPS™ Baby Plating system	Mandibular fractures (7 symphysis and body); Zygomatic complex fractures (2); craniosynostosis (1); hemifacial microsomia (1); antral window (1)	12 children aged 6 months to 14 years	8 months	1. Fracture stability and healing were achieved 2. No major local reaction or impairment of skeletal growth was observed
Inion CPS™ Baby	Senel et al. (2006) Treatment of a mandibular fracture with biodegradable plate in an infant: Report of a case Oral Surg Oral Med Oral Pathol Oral RadiolEndod 2006;101:448-50	Case study (case report): The management of a fracture of the mandible in an 8-month-old infant using a biodegradable plate and screws with open reduction	Inion CPS ® Baby 1.5 mm Plating system	Mandibular fractures	1 infant	8 months	1. The healing of fracture was satisfactory without any deformities, functional restrictions, or complications 2. No displacement with lateral flaring of the mandibular angles

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Inion CPS™ Baby	Losken et al. (2008) Biodegradation of Inion® fast-absorbing biodegradable plates and screws J Craniofacial Surg 2008; 19(3):748-756	Preclinical Study: The biodegradation rate of Inion CPS™ Baby biodegradable plates and screws under different clinical circumstances in the rabbit craniofacial skeleton and their efficacy for use in pediatric craniofacial surgery	Inion CPS™ Baby 1.5 mm Plating system	Frontal bone hole and fractures	30 Rabbits	18 months	1. Effective biodegradation of the plates and screws had occurred by 12 months 2. Inion CPS™ Baby plates are appropriate for use in rigid fixation of the pediatric craniofacial skeleton
Inion CPS™	Jeon et al. (2016) Delayed Foreign Body Reaction Caused by Bioabsorbable Plates Used for Maxillofacial Fractures Arch Plast Surg 2016;43:40-45	Clinical study: Maxillofacial fractures, in which rigid fixation was achieved with bioabsorbable plating systems	Inion CPS™ 1.5 mm and 2.0 mm Plating system (and Synthes RapidSorb® Plating system)	A total of 234 patients who were treated using bioabsorbable plates were included in our study. They were diagnosed with a zygomaticomaxillary complex fracture (n=146), maxilla fracture (n=57), nasoethmoid orbital fracture (n=20), or a LeFort fracture (n=11). Rigid fixation was achieved with the Inion CPS Plating system in 173 patients	234 patients between 15 – 84 years. 173 patients in the Inion CPS™ group	9–23 months	Complications occurred in eight (3.4%) of 234 patients, including palpable, fixed masses in six patients and focal swelling in two patients. The period from surgical fixation to the onset of symptoms was 9–23 months. Six patients with a mass underwent secondary surgery for mass removal. Patients with an isolated, noncomminuted, minimally displaced fracture were good candidates for bioabsorbable fixation. However, biodegradable plates were regarded as the most appropriate in young patients irrespective of the fracture type.
Inion CPS™	Singh et al. (2016) Management of pediatric mandibular fractures using bioresorbable plating system – Efficacy, stability, and clinical outcomes: Our experiences and literature review Journal of oral biology and craniofacial research 6 (2016) 101-106	Clinical study: Efficacy and stability of the biodegradable fixation system in the treatment of pediatric mandible fractures	Inion CPS™ 2.5 mm Plating system	Mandibular fractures, 55% of the mandibular fractures were in body, 25% at angle, and 20% in the parasymphyseal region	60 pediatric patients between 8–15 years	10 months	1. Adequate fixation and primary bone healing was achieved in 100% of the cases. Six minor complications (10%) were observed: 2 soft tissue infections (3%), 1 plate dehiscence (2%), 1 malocclusion (2%), and 2 paresthesia (3%) 2. 2.5-mm resorbable plating system along Champy's line of ideal osteosynthesis is a good treatment modality for mandible fractures in pediatric patients

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Singh et al. (2012) Bio-Resorbable Plates as Effective Implant in Pediatric Mandibular Fracture J. Maxillofac. Oral Surg. (Oct-Dec 2012) 11(4): 400–406	Clinical study: The efficacy and importance of using biodegradable plates in pediatric mandibular fractures	Inion CPS™ 2.0 mm and 2.5 mm Plating system	Mandibular fractures	40 pediatric patients, most commonly 6 to 10 years, mean age 9.2 years	2 weeks, 1, 3 and 6 months	1. Bioresorbable plates in pediatric mandibular fracture was efficacious enough to bear the masticatory loads during osteosynthesis of the fracture 2. In this study there was no complication and no growth disturbance in mandible and also the bite force recorded in follow up period was suggestive of bioresorbable plate are proven to be stable fixation in children
Inion CPS™	Bali et al. (2013) To evaluate the efficacy of biodegradable plating system for fixation of maxillofacial fractures: A prospective study. Natl J Maxillofac Surg 2013; Jul-Dec; 4(2): 167–172	Clinical study: Midface fractures in adults and mandibular fractures with pediatric patients	Inion CPS™ 2.0 mm and 2.5 mm Plating system		10 patients (8 adults and 2 children), age 6–45 years, average age 32.8 years	1, 4, 12 and 24 weeks	1. Favorable healing can be observed through the use of biodegradable plates and screws to stabilize selected midface fractures in patients of all ages, as well as mandible fractures in early childhood 2. Post-operative reduction and stability of the fracture segments was maintained in all the patients throughout the follow-up period which reflects upon the strength of the bioresorbable plates and screws which maintains reduction and provides enough stability for healing to take place 3. In the present study, none of the patient had wound dehiscence and plate exposure in the post-operative period
Inion CPS™	Elhalawany et al. (2015) Clinical and radiographic evalauation of biodegradable bone plates in the treatment of mandibular body fractures. Niger Med J 2015; Jan-Feb; 56(1): 48–53	Clinical study: Mandibular body fractures	Inion CPS™ Plating system		8 patients	1 week, 1, 3 and 6 months	1. Healing process was comparable with previously reported by titanium bone plates 2. MMF was applied for 1 week post-op. Soft diet for 2 weeks post op 3. No abnormal pain, swelling or discharge during post op time 4. All patients showed some degree of deranged occlusion on admission, good occlusion was achieved in all patients post op

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Van Bakelen et al. (2014) Comparison of the long-term skeletal stability between a biodegradable and a titanium fixation system following BSSO advancement – A cohort study based on a multicentre randomised controlled trail British Journey of Oral and Maxillofacial Surgery 2014; 52: 721-728	Clinical study: Comparison of the long-term skeletal stability between a biodegradable and a titanium fixation system following BSSO advancement	Inion CPS™ 2.5 mm Plating system 2.0 mm titanium, plates and screws	Advancement bilaterial sagittal split osteotomies (BSSO)	15 patients in biode-gradable group, and 22 in the titanium group	2 years	1. No significant difference in the postoperative skeletal stability was found between biodegradable group and titanium group 2. Stabilization of Le Fort I advancement with polylactate bioresorbable and titanium devices produced similar clinical outcomes at 1 year following surgery
Inion CPS™	Lim et al. (2014) Comparison of resorbable plates and titanium plates for fixation stability of combined mandibular symphysis and angle fractures J Korean Assoc Oral Maxillofac Surg 2014; 40(6):285-290	Clinical study: Comparison of resorbable plates with titanium plates for treatment of combined mandibular angle and symphyseal fractures	Inion CPS™ Plating system	Combined mandibular angle and symphysis fractures	13 patients (R group, 39 resorblable plates) and 16 patients (T group, 48 titanium plates)	Up to 3 months	1. Resorbable plates have the comparable clinical outcomes with metal plates. 2. All infections occurred within 1 month and disappeared by antibiotic therapy 3. The treatment goals of immobilization, fixation, and stabilization were fulfilled. 4. Resorbable plates can be use as an alternative to titanium plates in combined mandibular angle and symphysis fractures
Inion CPS™	Yu et al. (2014) Can resorbable screws effectively be used in fixating bilateral sagittal split osteotomies for mandibular advancement? A randomized controlled trail J Oral Maxillofac Surg 2014; 72: 2273-2277	Clinical study: The efficacy of resorbable screws in fixation of bilateral mandibular sagittal split osteotomies (BSSOs)	Inion CPS™ Screws	BSSOs for correction of retrognathic mandibles	101 patients (51 in non-resorbable group, 50 in resorbable group)	9.050 ± 8.306 months	1. The resorbable screws provides comparable fixation as titanium in fixating BSSO advancements 2. The clinical results show no difference in rate of relapse, postoperative infection or inflammation, having to reoperate, and no difference in maximal incisal opening

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Inion CPS™	Ballon et al. (2011) Patients' expectations and postoperative satisfaction of dysgnathic patients operated on with resorbable osteosyntheses J Craniofac Surg 2011; 22:730-4	Patient satisfaction study	General absorbable products	Dysgnathic and occlusal malocclusion	50 patients	Ques-tionnaire finished at: preoperative -2 to 6 weeks before the operation; postoper-ative -4 to 8 weeks after the operation; follow-up -11 to 14 months after the operation	1. Due to the avoidance of secondary surgery, 94% of patents chose resorbable osteofixations although a mere 66% had heard of them before; 90% of patients were satisfied with the operation result
Inion CPS™	Vazquez-Morales et al. (2013) Treatment of mandible fractures using resorbable plates with a mean of 3 weeks maxillomandibular fixation: a prospective study Oral Surg Oral Med Oral Pathol Oral Radiol. 2013; 115(1):25-28	Clinical study: Clinical assessment of 2.5mm Inion CPS™ Plating system for the fixation of mandibular fractures with 3 weeks of maxillomandibular fixation	Inion CPS™ 2.5 mm Plating system	Mandibular fractures (24 angle fractures, 16 parasymphysis fractures, 9 body fractures, and 1 symphysis)	34 patients with 50 mandibular fractures	5 days to 6 weeks	1. The Inion CPS™ Biodegradable Fixation System is a viable option for the treatment of noncomminuted and noninfected mandible fractures with successful healing in 100% of cases
Inion CPS™	Lee et al. (2014) 3D vector analysis of mandibular condyle stability in mandibular setback surgery with bicortical bioabsorbable screw fixation J Craniomaxillofac Surg 2014. 42(5):e105-110	Clinical study: The evaluation of the surgical stability of biocortical absorbable screw fixation using 3D vector analysis	Inion CPS™ 2.5 mm Plating system	Mandible prognathism	30 patients	6 months	1. In 3D vector analysis, bioabsorbable screw fixation in SSRO with distal segment osteotomy shows clinically acceptable postoperative condylar position stability

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Yu and Bloomquist (2013) Randomized prospective clinical trial on use of resorbable screws in fixating bilateral sagittal split osteotomies for mandibular advancement Poster: 95th Annual Meeting, Scientific Sessions and Exhibition in conjunction with the british Association of Oral and Maxillofacial Surgeons	Clinical study: The comparison between resorbable plating system and titanium system in orthognathic surgery	Inion CPS™ Plating system	Mandibular retrognathia	101 Patients (50 in resorbable group, 51 in titanium group)	8–11 months	1. Resorbable screws can be used effectively for fixation of BSSO for mandibular advancement and require no second procedure for screw removal 2. No relapse has been found after the completion of treatments in patients who received resorbable screws 3. No significant difference in infection/ inflammation rate and operative maximal incisal opening was observed between the two groups
Inion CPS™	Paeng et al. (2012) Comparative study of skeletal stability between bicortical resorbable and titanium screw fixation after sagittal split ramus osteotomy for mandibular prognathism J Craniomaxillofac Surg 2012 Dec; 40(8):660-4	Clinical study: The skeletal stability of bicortical resorbable screw fixation after sagittal split ramus osteotomies for mandibular prognathism	Inion CPS™ 2.5 mm Plating system	Mandibular prognathism	50 patients (25 in bioresorb-able group and 25 in Titanium group)	12–22 months	1. No significant difference was observed in postoperative skeletal stability between bioresorbable and titanium groups 2. No major intraoperative complications 3. Bicortical resorbable screws offer a clinically stable outcome for the fixation of mandibular sagittal split osteotomies in mandibular prognathism
Inion CPS™	Atali et al. (2011) Assessment of biomechanical stability, stress distribution and resorption patterns of biodegradable 2.0mm Inion® CPS fixation system in a rabbit model J Oral Maxillofac Surg 2011; 69(9)	Biomechanical Stability	Inion CPS™ 2.0 mm Plating system	Bilateral mandibular vertical body osteotomies (BMVBO)	15 Rabbits	3 months	1. Maximum loads were 89.4 N, 41.0 N and 13.8 N in follow up session respectively in a servohydraulic testing unit (STU) 2. Bone healing varies along the osteotomy site fixed by resorbable system, depending on the healing periods, the action of tension and compression forces generated by mastication
Inion CPS™	Rock et al. (2011) Evaluation of the Inion resorbable plating system for Open Reduction Internal Fixation (ORIF) of mandible fractures Anesthesia Conference Poster 66	Clinical study: The efficacy of Inion CPS™ in the treatment of mandible fractures in conjunction with 3 weeks of MMF	Inion CPS™ 2.5 mm Plating system	Mandible Fractures: angle (24), parasymphysis (16), body (9), and symphysis (1)	34 patients with a total of 50 fractures	10 months	1. The Inion CPS™ Biodegradable Fixation System is a viable treatment option for ORIF of mandible fractures with three weeks of MMF

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Inion CPS™	Baek et al. (2011) The perilobule approach to subcondylar fractures Ann Plast Surg 2011; 66(3):253-6	Clinical Study (surgery approach)	Inion CPS™ 1.5 to 2.0 mm absorbable Plating system	Subcondylar fractures	17 patients	6 months (range 5–28 months)	1. Good temporomandibular joint function in all patients, nerve branches well preserved, invisible scarring 2. The short perilobe approach (the incision line locates just anterior and posterior to the ear lobe) achieves good exposure of the fractured condyle, shortens the procedure time and heals with a barely perceptible scar
Inion CPS™	Bhatt et al. (2010) Equivalence randomized controlled trial of bioresorbable versus titanium miniplates in treatment of mandibular fracture: a pilot study J Oral Maxillofac Surg 2010 Aug;68(8):1842-8	Clinical Study: Comparison in fixation between bioresorbable and titanium products in terms of clinical union and complications	Inion CPS™ 2.5 mm Plating system Titanium system (SynthesGmBh, Oberdorf, Switzerland) 2.0mm locking plates and screws	Mandibular Fracture	40 Patients (19 in bio-resorbable group, 21 in titanium group)	8 weeks	1. The avoidance of repeat surgery for plate removal is a definite advantage of using resorbable plates
Inion CPS™	Bayat et al. (2010) Treatment of mandibular angle fractures using a single bioresorbable miniplate J Oral Maxillofac Surg 2010; 68:1573-1577	Clinical Study: Adequate fixation with minor complications	Inion CPS™ 2.5 mm 6-hole plate	Unilateral mandibular angle fractures	19 patients (15–41 years old)	2 years	1. Clinical outcomes: no mobility of plates; no dehiscence; no nonunion and minor complications 2. Specific advantages: radiolucent, easily shapeable plates without bending instruments, no need for removal operation, less effects on growth of mandible compared to nonresorbable plates, effective fixation in pediatric, safe in orthognathic procedures
Inion CPS™	Nazım (2009) The fate of an extruded biodegradable mandibular plate Journal of Plastic Reconstructive and Aestethic Surgeons, 2009; 62(6): 850-852	Case study: The fate and effect of an extruded biodegradable mandibular plate on the bone healing without performing any surgical intervention	Inion CPS™ 2.5 mm Plating system	Symphysis mandible fracture	1 patient	2 years	1. The possible complication such as extrusion and infection may have a minimal effect on bone healing 2. No interference on the fracture union 3. If there is no movement at the fracture site, a conservative approach to the management of an exposed plate or screws may be an alternative choice to re-operation

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Inion CPS™	Leonhardt et al. (2008) INION compared with titanium osteosynthesis:a prospective investigation of the treatment of mandibular fractures British Journal of Oral and Maxillofacial Surgery 2008;46(8): 631–634	Clinical study: Comparison between resorbable plating system and titanium system in the treatment of mandibular fractures	Inion CPS™ 2.0 and 2.5 mm Plating systems and 2.0 mm Titanium system	Mandibular fractures in biodegradable group (BG, 1 symphysea, 14 parasymphysea, and 22 of the mandibular angle) Mandibular fractures in titanium group (TG, 21 parasymphsea and 23 mandibular angle)	60 patients (30 in RG, 37 fractures; and 30 in TG, 44 fractures)	6 months	1. All the fractures in both groups healed both clinically and radiologically 2. Comparable inpatient treatment time of the patients 3. After 6 months all patients had perfect occlusions in both groups 4. Inion CPS™ plates were biocompatible and strong enough to treat mandibular fractures.
Inion CPS™	Canter and Mavili (2007) Bicortical biodegradable screws for rigid fixation of traumatic sagittal split mandibular fracture J Craniofac Surg 2007 May;18(3):626-9	Case study: The technique of bicortical screw fixation of split osteotomy using absorbable system	Inion CPS™ 2.8 mm Screws	Mandibular sagittal oblique fracture	1 patient	9 months	1. Use of biodegradable screws seems to be safe for rigid bone fixation in selected oblique mandibular fractures 2. Dramatically shortened operative time; Cost effective compared to titanium screw and plating system; Lower profile of screw head can prevent from tissue protruding
Inion CPS™	Laughlin et al. (2007) Resorbable plates for the fixation of mandibular fractures: A prospective study J Oral Maxillofac Surg 2007; 65:89-96	Clinical study: To evaluate if resorbable plates are equal to the performance of titanium 2-mm plates, regarding healing of the fracture and restoration of function	Inion CPS™ 2.5 mm Plating system	Mandibular fractures: angle fractures, body fractures, parasymphyseal fractures and symphysis fractures	35 patients (50 fractures)	8 weeks	1. Clinical and radiographic evaluation indicated clinical union of all fractures at the 8-week follow-up
Inion CPS™	Yang et al. (2014) Skeletal stability of bioresorbable fixation in orthognathic surgery: A systemic review J Craniomaxillofac Surg 2014; 42: e176-81	Literature review of the effectiveness of bioresorbable fixation systems compared to titanium systems used for orthognathic surgery	Inion CPS™ 2.5 mm Plating system	Bilateral sagittal split ramus osteotomy (BSSRO), Le Fort I, Bimaxillary operation, Mixed	20 articles involving 1092 participants	2–96 months	1. Twenty studies, published between 1997 and 2012, involving 1092 participants show that bioresorbable fixation systems produce reliable skeletal stability.

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Sverzut et al. (2012) Comparative study of bone repair in mandibular body osteotomy between metallic and absorbable 2.0 mm internal fixation systems. Histological and histometric analysis in dogs: a pilot study Int J Oral Maxillofac Surg 2012 ; 41(11):1361-8	Preclinical study: The comparison of bone repair along a mandibular body osteotomy stabilized with absorbable and metallic system	Inion CPS™ 2.0 mm Plating system and metallic system	-	12 dogs	18 weeks	1. At osteotomy site, metallic system promotes the growth of more compact bone whereas the absorbable system assists the healing of spongy bone
Inion CPS™	Nieminen et al. (2008) Degradative and mechanical properties of a novel resorbable plating system during a 3-year follow-up in vivo and in vitro J Mater Sci: Mater Med 2008;19:1155-1163	Preclinical and Biomechanical study: The degradation and mechanical strength of Inion CPS™ system in vivo and in vitro	Inion CPS™ 2.0–2.5 mm Plating system	-	12 sheep	6–156 weeks	1. The examined plates and screws maintain adequate strength for the healing period of a bone fracture or osteotomy (6-12 weeks) 2. Degradation in two years without producing harmful foreign body reactions 3. Implants in mandible were found to be replaced by bone
Inion CPS™	Hwang et al. (2012) Effect of number and geometry of resorbable screws on biomechanical stability of in vitro model with sagittal split ramus osteotomy J Craniofac Surg 2012;23: 363-366	Biomechanical test: The effect of the numbers and the geometry of resorble screws (RSs) on the biomechanical Stability of the in vitro model with sagittal split ramus osteotomy	Inion CPS™ 2.8 mm Screws	Any indications for rigid fixation of the mandible after the sagittal split ramus osteotomy	-	-	1. According to the number and geometry of RSs, fixation with 3 RSs in the retromolar area (RMA) and the mandibular angle (MA) (2 RSs at the RMA and 1 RS at the MA, 2R1A) could provide better biomechanical stability than titanium miniplate and screws (1 titanium miniplate and 4 screws, 1TP) and similar stability with 5 RSs (3 RSs at the RMA, 1 RS at the MA, and 1 RS at the mandibular body, 3R1A1B)
Inion CPS™	You et al. (2013) 2-year follow-up on the use of absorbable mesh plates in the treatment of medial orbital wall fractures Arch Plast Surg 2013;40:728-734	Clinical study: The feasibility of using Inion CPS™ Plating system for medial orbital wall reconstruction	Inion CPS™	Medial orbital wall fractures	44 patients (20 patients underwent follow up)	2 years	1. No major complications 2. The mesh plate may provide a supportive scar or de novo septum to the orbital contents even after the absorbable materials have dissolved completely 3. Absorbable plate can be used as an option for the reconstruction of the medial orbital wall

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Inion CPS™	Hwang et al. (2010) A use of Poly-L-Lactide, D-Lactide sheet on posterior orbital floor fracture J Craniofac Surg 2010;21: 1221-1223	Clinical study: The safety of repairing the orbital posterior floor using Inion CPS™ mesh	Inion CPS™ Mesh plates	Orbital posterior wall fractures	6 patients	1 month to 1 year	1. The sheet implant was easily shaped and bent to adapt the inferior orbital rim 2. Clinical enophthalmos was significantly relieved, further safely repairing the orbital posterior floor fracture
Inion CPS™	Hwang and Kim (2010) Comparison of the supporting strength of a Poly-L-Lactic acid sheet and porous polyethylene (Medpor) for the reconstruction of orbital floor fractures J Craniofac Surg 2010;21: 847-853	Biomechanical test: Comparison between the supporting strength of the curved Inion CPS™ sheet and Medpor for reconstruction of orbital floor fractures	Inion CPS™ 1.5 mm Mesh plates	One-half and two-thirds orbital floor fractures	-	-	1. The absorbable sheet (Inion CPS™) and Medpor could support the internal orbital contents for reconstruction of extensive orbital floor fractures, with the former providing greater rigidity
Inion CPS™	Hwang and Hwang (2009) Do we have to dissect infraorbital nerve from periorbita in orbital floor fracture? J Craniofac Surg 2009;20: 1-3	Clinical study: The orbital fracture fixed by a horseshoe shaped synthetic sheet without separating the periorbital from the infraorbital never	Inion CPS™ Plating system (trimmed in horseshoe shape)	Orbital floor fracture	31 patients	1 year	1. 9.7% of postoperative complication rate 2. In the follow-up, all patients with complication were improved by 6 months without reoccurring
Inion CPS™	Hwang (2009) Medial orbital wall reconstruction through subciliary approach: Revisit J Craniofac Surg 2009; 20 (4): 1280-1282	Clinical study: The safety and complication of subciliary approach using resorbable polylactic acid sheet or porous polyethylene sheet	Inion CPS™ Mesh plates (trimmed and molded in L shape)	Medial orbital wall fractures	30 patients (8 using Medpor sheet, 22 using Inion CPS™)	1 year	1. No complaints of visible scar 6 months postoperatively 2. No ectropion 3. The postoperative complication rate was 10% and all complications were improved by 3-6 months without reoccurring

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Hwang et al. (2009) Analysis of orbital bone fractures: A 12-year study of 391 patients J Craniofac Surg 2009 ;20(4):1218-23	Clinical study: The comparison of clinical outcomes between porous polyethylene sheet and resorbable sheet groups	Inion CPS™ 1.5 mm Plating system (41.1%) MEDPOR (56.4%)	Isolated orbital bone fracture	391 patients	1 year	1. No difference in clinical outcomes and complication rate between two groups
Inion CPS™	Tuncer et al. (2007) Technical experiences reconstruction of traumatic orbital floor fractures with resorbable mesh plate J Craniofac Surg 2007;18(3):598-605	Clinical study: The safety and value of the use of resorbable mesh plate in the treatment of orbital floor fracture	Inion CPS™ 1.5 mm Plating system	Orbital floor fractures	17 patients	3–28 months	Advantages of resorbable mesh plates used for orbital floor reconstructions: 1. It is easy to sculpt to fit to the defect and the operation time was significantly decreased 2. Low profile prevents postoperative proptosis and globe dystopia 3. Maintenance of orbital contents against herniation forces during the initial phase of healing and complete resorption from the region after it is no longer needed (most important superiority)
Inion CPS™	Sadigh et al. (2014) The “in situ molding technique.” An accurate and simple way to fix resorbable plates to the facial skeleton J Craniofac Surg 2014; 25: 1766–1768	Clinical study: The clinical result of facial fracture fixation when Authors used hot water suction irrigation to achieve in situ molding of resorbable plates during operation.	Inion CPS™ Plating system	Facial fractures: Zygo-maticomaxillary complex; Mandibular; Fronto-zygomaticomaxillary; Zygo-maticomaxillary mandibular; Fronto-zygomaticomaxillary mandibular	110 patients with age range from 6 to 70 years	Over 4-year period	1. In situ molding technique described provided patients with very satisfying results and simplified the application process of biodegradable plate to the facial skeleton for the surgeon. 2. No complications secondary to the use of hot water suction irrigation were found

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Blakey et al. (2014) Are bioresorbable polylactate devices comparable to titanium devices for stabilizing Le Fort I advancement? Int. J. Oral Maxillofac Surg 2014;43,4: 437–444	Clinical study: Comparison in stabilization after Le Fort I surgery between bioresorbable and titanium products	Inion CPS™ 2.0 mm Plating system 2.0 mm titanium orthognathic system	Isolated maxillary advancement	57 patients (27 in resorbable group (R), 30 in titanium group(M))	1 year	1. More mobility of maxilla in resorbable group was noted during the first several months following surgery. (R plates are less rigid than M plates which may be advantageous to the completion of postsurgical orthodontic treatment since elastic traction can effect skeletal and dental movements) 2. Similar clinical outcomes were produced in both groups (R and M) and there was no clinical and statistical difference in outcomes between the groups
Inion CPS™	Landes et al. (2013) Evaluation of the fatigue performance and degradability of resorbable PLDLLA-TMC osteofixations The Open Biomedical Engineering Journal 2013, 7, 133-146	Preclinical and in situ patient studies: The Fatigue Performance and Degradability of explants and virgins (Inion CPS™ Plating System)	Inion CPS™ 2.0 mm Plating system	Maxillary or mandible fractures and osteotomies	18 patients (21 explants)	3–6 months	1. The failure load decreased dramatically after 4 months in situ 2. The surface showed the sign of degradation after 4,5 months in situ and cracks and pores appeared after 9 months in situ 3. Inion CPS™ system are stable enough to allow loading of the healing bone and degrade reliably
Inion CPS™	Degala et al. (2013) Fixation of zygomatic and mandibular fractures with biodegradable plates Annals of Maxillofacial Surgery 2013; 3(1):25-30	Clinical study: Assessment of the fixation of zygomatic complex and mandibular fractures with Inion CPS™	Inion CPS™ 1.5/2.0/2.5 mm Plating system	Zygomatic-complex fractures (2 site fractures) and mandibular fractures	13 patients (5 zygomatic fractures; 8 mandibular fractures: 7 para-symphysis and 1 angle fracture)	6 months–1,5 year	1. Inion CPS™ system fulfilled the treatment goals of adequate immobilization fixation and stabilization of zygomatic-complex and mandibular fractures 2. Stability of the fracture fragments and handling characteristics of Inion CPS™ were comparable with metal system 3. Advantages compared to metal system: Avoidance of second surgery due to resorption, less interference in craniofacial growth in children, and less interference with computed tomographic or magnetic resonance imaging

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Kim et al. (2012) Treatment of frontal sinus fracture using bioabsorbable mesh plates J Craniofac Surg 2012;23: 549-551	Clinical study: The feasibility of bioresorbable plates and screws for the treatment of frontal sinus fracture	Inion CPS™ 1.5 mm Mesh plate and screw	Frontal sinus fracture (Anterior table, Anterior /Posterior table fractures)	14 patients	6–33 months	1. Absorbable mesh plates are relatively thin, convenient for screw fixation, and easy to mold and trim 2. No need for removal operation 3. Aesthetic appearance and no remarkable early and late postoperative complication during a long follow up 4. Suitable fixation for mild to moderate degree of frontal bone fractures, instead of metal implants
Inion CPS™	Ballon et al. (2012) Segmental stability of resorbable P(L/DL) LA-TMCosteosynthesis versus titanium miniplates in orthognatic surgery J Craniomaxillofac Surg 2012 ;40(8):e408-14	Clinical Study: The comparison of stability with the use of titanium miniplates and Inion CPS™ miniplates	Inion CPS™ 2.0 mm Inion CPS™ 2.5 mm Standard titanium osteosynthese (2,0 mm standard Wurzburg miniplate system; Stryker-Leibinger, Tuttlingen, Germany)	Maxillary Mandibular osteosynthese	84 patients (41 in the study group: 38 bimaxillary surgery, 3 Le Fort I osteotomy *43 in the control group: 24 biomaxillary surgery, 15 Le Fort I osteotomy, 4 BSSO)	Approx. 12 months Study Group: mean radiological follow up: 13 months Control Group: mean radiological follow up: 35 months	1. Biocompatibility: In the INION CPS™ group, no foreign body granuloma occurred throughout this study (slow resorption over 2 years) 2. Stability: INION CPS™ systems can be used in the most movement directions; Be comparable to titanium miniplates regarding stability, bearing in mind the higher relapse in maxillary elongation and mandibular setback 3. Clinical Outcomes: Resorbable INION CPS™osteosynthesis can be used with equivalent outcomes to titanium miniplates except in maxillary elongation and mandibular setback; Overcompensation and longer intermaxillary retention are needed in these directions
Inion CPS™	Kim and Kim (2011) Fractured facial bone reduction and resorbable plate fixation using tapper J Craniofac Surg 2011;22: 1215-1218	Clinical study: The novel simplified handling method for resorbable plate fixation - inserting bone tap as a temporary metal screw	Inion CPS™ Plating system	Maxillary fractures: Frontal bone fracture; Zygoma-complex fracture; Maxillary anterior wall fracture; Blowout fracture; Mandible fracture	68 patients (106 facial bone fractures)	2–12 months	1. The operation became more simple and accurate by using the bone tap as an instrument for reduction and fixation of fracture fragment 2. Stability was ensured during fixation 3. No major complications

Product	Reference	Study Type	Product Use	Medical Condition	N	Follow-up	Outcomes
Inion CPS™	Singh et al. (2011) Evaluating the applicability of a biodegradable osteosynthesis plating system in the management of zygomatico-maxillary complex fractures Otolaryngology– Head and Neck Surgery 2012;145(6): 924–929	Clinical study: The efficacy of bioresorbable plates and screws in internal fixation of zygomatico-maxillary complex (ZMC) fractures and the incidence of complications associated with the procedure	Inion CPS™ 1.5/2.0 mm Plating system	Zygomatico-maxillary complex (ZMC) fractures	14 patients	6 months	1. The biodegradable osteosynthesis system exhibits adequate strength and has negligible complications
Inion CPS™	Turvey et al. (2011) Biodegradable fixation for craniomaxillofacial surgery: a 10-year experience involving 761 operations and 745 patients Int. J. Oral Maxillofac Surg 2011; 40: 244–249	Clinical study: Patient acceptance, safety, and efficacy of poly-L/DL-lactic acid (PLLDL) bone plates and screws in craniomaxillofacial surgery	Inion CPS™ Plating system	Osteotomies; Reconstruction; Trauma in the craniomaxillo-facial area (midface, forehead, mandible)	745 Patients	4 years	1. PLDLA can be used safely and successfully (94%, no material breakage or an acute inflammatory response during the biodegradation phase) for craniomaxillofacial surgical applications, especially maxillary and mandibular osteotomy stabilisation 2. Patient appeal is very high (98%) and the need for second operations to remove or replace this material is only 6% 3. Bone healing was noted at all sites
Inion CPS™	Cheung et al. (2008) Stability and morbidity of Le Fort I osteotomy with bioresorbable fixation: a randomized controlled trial Int. J. Oral Maxillofac Surg 2008; 37: 232–241	Clinical study: The comparison between the use of bioresorbable and titanium mini-plates and screws in Le Fort I maxillary osteotomies for evaluation of clinical morbidity and stability	Inion CPS™ 2.0 mm Plating system	Dento-facial deformities	20 patients	12 months	1. Comparable horizontal and angular relapses treated with the Inion CPS™ and titanium plating systems 2. No differences in complications between the two groups

References

ANDREASSEN, G. S., KAINONEN, T., BRINK, O. & KURKINEN, M. Healing of Ankle Fractures: Comparison of Biodegradable and Metal Plate and Screws. AAOS 2008 Annual Meeting, 2008 San Francisco, California.

ATALI, O., VAROL, A., BASA, S., AK, E., ERGUN, C. & CETINEL, S. 2011. Poster 49: Assessment of Biomechanical Stability, Stress Distribution and Resorption Patterns of Biodegradable 2.0mm Inion® CPS Fixation System in a Rabbit Model. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons, 69, e80.

BAEK, R. M., MIN, K. H., HEO, C. Y. & EUN, S. C. 2011. The perilobule approach to subcondylar fractures. Ann Plast Surg, 66, 253-6.

VAN BAKELEN, N. B., BOERMANS, B. D. A., BUIJS, G. J., JANSAMA, J., PRUIM, G. J., HOPPENREIJS, TH. J. M., BERGSMA, J. E., STEGENGA, B. & BOS, R. R. M. 2014. Comparison of the long-term skeletal stability between a biodegradable and a titanium fixation system following BSSO advancement - A cohort study based on a multicentre randomised controlled trail. British Journal of Oral and Maxillofacial Surgery 52: 721-8.

BALI, R. K., SHARMA, P., JINDAL, S., GABA, S. 2013. To evaluate the efficacy of biodegradable plating system for fixation of maxillofacial fractures: A prospective study. Natl J Maxillofac Surg, Jul-Dec; 4(2): 167–172.

BALLON, A., LAUDEMANN, K., SADER, R. & LANDES, C. A. 2011. Patients' preoperative expectations and postoperative satisfaction of dysgnathic patients operated on with resorbable osteosyntheses. J Craniofac Surg, 22, 730-4.

BALLON, A., LAUDEMANN, K., SADER, R. & LANDES, C. A. 2012. Segmental stability of resorbable P(L/DL)LA-TMC osteosynthesis versus titanium miniplates in orthognatic surgery. J Craniomaxillofac Surg, 40, e408-14.

BAYAT, M., GARAJEI, A., GHORBANI, K. & MOTAMEDI, M. H. 2010. Treatment of mandibular angle fractures using a single bioresorbable miniplate. J Oral Maxillofac Surg, 68, 1573-7.

BHATT, K., ROYCHOUDHURY, A., BHUTIA, O., TRIKHA, A., SEITH, A. & PANDEY, R. M. 2010. Equivalence randomized controlled trial of bioresorbable versus titanium miniplates in treatment of mandibular fracture: a pilot study. J Oral Maxillofac Surg, 68, 1842-8.

BLAKEY, G. H., ROSSOUW, E., TURVEY, T. A., PHILLIPS, C., PROFFIT, W. R. & WHITE, R. P. 2014. Are bioresorbable polylactate devices comparable to titanium devices for stabilizing Le Fort I advancement? Int J Oral Maxillofac Surg, 43, 437-44.

CAMPBELL, N., CONAGLEN, P., MARTIN, K., ANTIPPA, P. 2009. Surgical Stabilization of Rib Fractures Using Inion OTPS Wraps—Techniques and Quality of Life Follow-Up, The Journal of TRAUMA - Injury, Infection, and Critical Care, Volume 67, Number 3.

CANTER, H. I. & MAVILI, M. E. 2007. Bicortical biodegradable screws for rigid fixation of traumatic sagittal split mandibular fracture. J Craniofac Surg, 18, 626-9.

CHEN, M., Yang, S., Yang, C., Xu, W., Ye, S., Wang, J., Feng, Y., Yang, W., Liu, X. 2016. Outcomes observed during a 1-year clinical and radiographic follow-up of patients treated for 1- and 2-level cervical degenerative disease using a biodegradable anterior cervical plate. J Neurosurg Spine, 25:2015-212.

CHEUNG, L. K., YIP, I. H. & CHOW, R. L. 2008. Stability and morbidity of Le Fort I osteotomy with bioresorbable fixation: a randomized controlled trial. Int J Oral Maxillofac Surg, 37, 232-41.

CHOTEL, F., KNORR, G., SIMIAN, E., DUBRANA, F. & VERSIER, G. 2011. Knee osteochondral fractures in skeletally immature patients: French multicenter study. Orthop Traumatol Surg Res, 97, S154-9.

CHUKWUNYERENWA, C., MURPHY, T., CONNOLLY, P. & MCCORMACK, D. 2012. Use of bioabsorbable pin in innominate osteotomy for correction of developmental dyplasia of the hip. Journal of Bone & Joint Surgery, British Volume, 94-B, 148.

DAWSON, P. H., O'BRIAIN, D. E., CONNOLLY, P. J., MCCORMACK, D. 2014. Bioabsorbable pins for bone fixation in the less invasive innominate osteotomy. J Pediatr Orthop B. 2014 Sep;23(5):426-9.

DEGALA, S., SHETTY, S. & RAMYA, S. 2013. Fixation of zygomatic and mandibular fractures with biodegradable plates. Ann Maxillofac Surg, 3, 25-30.

EDMONDS, E. W. 2012. Use of an absorbable plate in the management of a clavicle fracture in an adolescent. Am J Orthop (Belle Mead NJ), 41, 29-32.

ELHALAWANY, S. K., TARAKJI, B., AZZEGHAIBY, SN., ALZOGHAIBI, I., BAROUDI, K., NASSAI, M. Z. 2015. Clinical and radiographic evaluation of biodegradable bone plates in the treatment of mandibular body fractures. Niger Med J, 56(1), 48-53.

FRANCO, A., NINA, P., ARPINO, L. & TORELLI, G. 2007. Use of resorbable implants for symptomatic cervical spondylosis: experience on 16 consecutive patients. J Neurosurg Sci, 51, 169-75.

FREEMAN, A. L., DERINCEK, A., BEAUBIEN, B. P., BUTTERMANN, G. R., LEW, W. D. & WOOD, K. B. 2006. In vitro comparison of bioresorbable and titanium anterior cervical plates in the immediate postoperative condition. J Spinal Disord Tech, 19, 577-83.

GAIARSA, G. P., DOS REIS, P. R., MATTAR JUNIOR, R., DOS SANTOS SILVA, J., & FERNANDEZ, T. D. 2015. Acta Ortop Bras 23 (5): 263-7

HAIMI, S., MOIMAS, L., PIRHONEN, E., LINDROOS, B., HUHTALA, H., RATY, S., KUOKKANEN, H., SANDOR, G. K., MIETTINEN, S. & SUURONEN, R. 2009. Calcium phosphate surface treatment of bioactive glass causes a delay in early osteogenic differentiation of adipose stem cells. J Biomed Mater Res A, 91, 540-7.

HORMOZI, A. K., SHAHVERDIANI, R., MOHAMMADI, H. R., ZALI, A. & MOFRAD, H. R. 2011. Surgical treatment of metopic synostosis. J Craniofac Surg, 22, 261-5.

HWANG, J. M., BAEK, S. H. & CHOI, J. Y. 2012. Effect of number and geometry of resorbable screws on biomechanical stability of in vitro model with sagittal split ramus osteotomy. J Craniofac Surg, 23, 363-6.

HWANG, K. 2009. Medial orbital wall reconstruction through subciliary approach: revisited. J Craniofac Surg, 20, 1280-2.

HWANG, K. & HWANG, J. H. 2009. Do we have to dissect infraorbital nerve from periorbita in orbital floor fracture? J Craniofac Surg, 20, 1260-2.

HWANG, K. & KIM, D. H. 2010. Comparison of the supporting strength of a poly-L-lactic acid sheet and porous polyethylene (Medpor) for the reconstruction of orbital floor fractures. J Craniofac Surg, 21, 847-53.

HWANG, K., KIM, D. H. & PARK, I. S. 2010. A use of poly-L-lactide, D-lactide sheet on posterior orbital floor fracture. J Craniofac Surg, 21, 1221-3.

HWANG, K., YOU, S. H. & SOHN, I. A. 2009. Analysis of orbital bone fractures: a 12-year study of 391 patients. J Craniofac Surg, 20, 1218-23.

IATROU, I., THEOLOGIE-LYGIDAKIS, N., TZERBOS, F. & ALEXANDRIDIS, K. 2006. The use of biodegradable plates in oral and maxillofacial surgery in children. Journal of Cranio-Maxillofacial Surgery, Volume 34 – Supplement 1 67.

Inion data on file testing report, T211R239/2016(2016). Antibacterial effect of bioactive glass 0608TTU agaist staphylococcus aureus ssp. Aureus ATCC BAA-44, Staphylococcus aureus ATCC 49230 and Staphylococcus epidermidis ATCC 51625. Biosafe- Biological Safety Solutions Ltd., Kuopio, Finland; May 2016.

JEON, H. B., KANG, D. H., GU, J. H., OH, S. A. 2016. Delayed Foreign Body Reaction Caused by Bioabsorbable Plates Used for Maxillofacial Fractures, Arch Plast Surg, 43:40-45.

JÄRVELÄ, S., KIEKARA, T., SUOMALAINEN, P., JÄRVELÄ, T. 2017. Double-bundle versus single-bundle anterior cruciate ligament reconstruction: A prospective randomized study with 10-year results. The American Journal of Sports Medicine, 45(11):2578-2585.

JÄRVELÄ, S., KIEKARA, T., JÄRVELÄ, T. 2016. Double-bundle versus single-bundle anterior cruciate ligament reconstruction: A prospective randomized study with 10-year results. The ACL study group 2016 Åre Meeting, Åre, Sweden, March 13-17, 2016; and The star paper session of the 17th ESSKA congress, Barcelona, Spain, May 4-7, 2016

JÄRVELÄ, S., SIHVONEN, R., SIRKEOJA, H. & JÄRVELÄ, T. 2010. All-Inside Meniscal Repair With Bioabsorbable Meniscal Screws or With Bioabsorbable Meniscus Arrows: A Prospective, Randomized Clinical Study With 2-Year Results. The American Journal of Sports Medicine, 38, 2211-2217.

JÄRVELÄ, T., MOISALA, A.-S., SIHVONEN, R., JÄRVELÄ, S., KANNUS, P. & JÄRVINEN, M. 2008a. Double-Bundle Anterior Cruciate Ligament Reconstruction Using Hamstring Autografts and Bioabsorbable Interference Screw Fixation: Prospective, Randomized, Clinical Study With 2-Year Results. The American Journal of Sports Medicine, 36, 290-297.

JÄRVELÄ, T., NURMI, J. T., PAAKKALA, A., MOISALA, A. S., KAIKKONEN, A. & JÄRVINEN, M. 2008b. Chapter 52 – Improving Biodegradable Interference Screw Properties by Combining Polymers. The Anterior Cruciate Ligament: Reconstruction and Basic Science. Saunders.

KIEKARA, T., JÄRVELÄ, T., HUHTALA, H., MOISALA, A. S., SUOMALAINEN, P. & PAAKKALA, A. 2014. Tunnel Communication and Increased Graft Signal Intensity on Magnetic Resonance Imaging of Double - Bundle Anterior Cruciate Ligament Reconstruction, Arthroscopy, 30, 1591-1601

KIEKARA, T., PAAKKALA, A., SUOMALAINEN, P., HUHTALA, H., JÄRVELÄ, T. 2017. Femoral and Tibial Tunnel Diameter and Bioabsorbable Screw Findings After Double-Bundle ACL Reconstruction in 5-Year Clinical and MRI Follow-up. The Orthopaedic Journal of Sports Medicine. 5(2), 2325967116685525.

KIM, C. H., KIM, D. H., KIM DA, H. & SONG, S. Y. 2012. Treatment of frontal sinus fracture using bioabsorbable mesh plates. J Craniofac Surg, 23, 549-51.

KIM, C. Y. & KIM, K. W. 2011. Fractured facial bone reduction and resorbable plate fixation using tapper. J Craniofac Surg, 22, 1215-8.

KUKK, A. & NURMI, J. T. 2009. A retrospective follow-up of ankle fracture patients treated with a biodegradable plate and screws. Foot Ankle Surg, 15, 192-7.

KURIKKA, H., AALTONEN, E. & GULLICHSEN, E. 2006. Syndesmosis fixation in the osteosynthesis of ankle injury at Turku University Central Hospital (TYKS). Ortopedia ja Traumatologia, 236-238.

LANDES, C., BALLON, A., GHANAATI, S., EBEL, D., ULRICH, D., SPOHN, U., HEUNEMANN, U., SADER, R. & JAEGER, R. 2013. Evaluation of the Fatigue Performance and Degradability of Resorbable PLDLLA-TMC Osteofixations. Open Biomed Eng J, 7, 133-46.

LAUGHLIN, R. M., BLOCK, M. S., WILK, R., MALLOY, R. B. & KENT, J. N. 2007. Resorbable plates for the fixation of mandibular fractures: a prospective study. J Oral Maxillofac Surg, 65, 89-96.

LEE, J. H., KIM, S. M., LEE, B. K., JEON, J. H. & KIM, M. J. 2014. 3D vector analysis of mandibular condyle stability in mandibular setback surgery with bicortical bioabsorbable screw fixation. J Craniomaxillofac Surg. 42(5):e105-10.

LEONHARDT, H., DEMMRICH, A., MUELLER, A., MAI, R., LOUKOTA, R. & ECKELT, U. 2008. INION compared with titanium osteosynthesis: a prospective investigation of the treatment of mandibular fractures. Br J Oral Maxillofac Surg, 46, 631-4.

LIM, H. Y., JUNG, C. H., KIM, S. Y., CHO, J. Y., RYU, J. Y., KIM, H. M. 2014. Comparison of resorbable plates and titanium plates for fixation stability of combined mandibular symphysis and angle fractures, J Korean Assoc Oral Maxillofac Surg 40:285-90.

LOSKEN, H. W., VAN AALST, J. A., MOONEY, M. P., GODFREY, V. L., BURT, T., TEOTIA, S., DEAN, S. B., MOSS, J. R. & RAHBAR, R. 2008. Biodegradation of Inion fast-absorbing biodegradable plates and screws. J Craniofac Surg, 19, 748-56.

MAVROGENIS, A. F., KANELLOPOULOS, A. D., NOMIKOS, G. N., PAPAGELOPOULOS, P. J., SOUCACOS, P.N. 2009. Early experience with biodegradable implants in pediatric patients. Clin Orthop Relat Res (2009) 467:1591–1598.

MOIMAS, L. In situ Tissue Engineering, effect of a porous bioactive glass scaffold on bone healing: in vivo rabbit study. 10th Meeting and Seminar on: Ceramics, Cells and Tissues - Materials for Tissue Engineering, Chemistry and Microstructure: The Role for Ceramics, 2006 Faenza. Consiglio Nazionale Delle Ricerche, 247-254.

MOIMAS, L., BIASOTTO, M., DI LENARDA, R., OLIVO, A. & SCHMID, C. 2006. Rabbit pilot study on the resorbability of three-dimensional bioactive glass fibre scaffolds. Acta Biomater, 2, 191-9.

NABHAN, A., ISHAK, B., STEIMER, O., ZIMMER, A., PITZEN, T., STEUDEL, W. I. & PAPE, D. 2009. Comparison of bioresorbable and titanium plates in cervical spinal fusion: early radiologic and clinical results. J Spinal Disord Tech, 22, 155-61.

NAM, S. M., KIM, Y. B., SHIN, H. S., PARK, E. S. & JUNG, S. G. 2011. Distraction osteogenesis with pivot plate in the treatment of scaphocephaly. J Craniofac Surg, 22, 96-9.

NAZIM, G. 2009. The fate of an extruded biodegradable mandibular plate. Journal of plastic, reconstructive & aesthetic surgery : JPRAS, 62, 850-852.

NIEMINEN, T., RANTALA, I., HIIDENHEIMO, I., KERANEN, J., KAINULAINEN, H., WUOLIJOKI, E. & KALLELA, I. 2008. Degradative and mechanical properties of a novel resorbable plating system during a 3-year follow-up in vivo and in vitro. J Mater Sci Mater Med, 19, 1155-63.

NOH, J. H., ROH, Y. H., YANG, B. G., KIM, S. W., LEE, J. S. & OH, M. K. 2012. Outcomes of operative treatment of unstable ankle fractures: a comparison of metallic and biodegradable implants. J Bone Joint Surg Am, 94, e166.

PAENG, J. Y., HONG, J., KIM, C. S. & KIM, M. J. 2012. Comparative study of skeletal stability between bicortical resorbable and titanium screw fixation after sagittal split ramus osteotomy for mandibular prognathism. J Craniomaxillofac Surg, 40, 660-4.

PENTON, J. L. & CASCIO, B. M. 2008. Internal Fixation of Osteochondritis Dissecans in the Knee. Operative Techniques in Sports Medicine, 16, 97-101.

POIRCUITTE, J. M., POPKOV, P., HUBER, D. H., POLIRSZTOK, E., LASCOMBES, P. & JOURNEAU, P. 2015. Resorbable osteosynthetic devices in pediatric traumatology: a prospective series of 24 cases, Eur J Ortop Traumatol, 25:997-1004.

ROCHER, H. 2007. A report of 89 Hallux Valgus Cases with 356 Inion OTPS™ Biodegradable Pins.

ROCK, A., HUDSON, C., VAZQUEZ, D. & LAZOW, S. 2011. Poster 66: Evaluation of the Inion Resorbable Plating System for Open Reduction Internal Fixation (ORIF) of Mandible Fractures. Journal of Oral and Maxillofacial Surgery, 69.

RODRIGO, V., MAZA, A., CALATAYUD, J.B., BANCES, L., DIAZ, F. J., GIMENO, M. J. & CARRO, B. 2015. Long-term of anterior cervical discectomy and fusion with bioabsorbable plates and screws. Clin Neurol Neurosur, 136, 116-21.

SADIGH, P. L., CHANG, L. R., FENG, K. M., & JENG, S. F. 2014. The `` in situ molding technique:'' an accurate and simply way to fix resorbable plates to the facial skeleton. J Craniofac Surg; 25: 1766-8.

SALOKORPI, N., SINIKUMPU, J-J, IBER, T., ZIBO, H. N., AREDA, T., YLIKONTIOLA, L., SANDOR, G. K. & SERLO, W. 2015. Frontal cranial modeling using endocranial resorbable plate fixation in 27 consecutive plagiocephaly and trigonocephaly patients. Childs Nerv Syst. 31(7): 1121-8.

SENEL, F. C., TEKIN, U. S. & IMAMOGLU, M. 2006. Treatment of a mandibular fracture with biodegradable plate in an infant: Report of a case. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology, 101, 448-450.

SERLO, W. S., YLIKONTIOLA, L. P., VESALA, A. L., KAARELA, O. I., IBER, T., SANDOR, G. K. & ASHAMMAKHI, N. 2007. Effective correction of frontal cranial deformities using biodegradable fixation on the inner surface of the cranial bones during infancy. Childs Nerv Syst, 23, 1439-45.

SINGH, G., MOHAMMAD, S., CHAK, R. K., LEPCHA, N., SINGH, N., MALKUNJE, L. R. 2012. Bio-Resorbable Plates as Effective Implant in Pediatric Mandibular Fracture. J. Maxillofac. Oral Surg. 11(4): 400–406.

SINGH, M., SINGH, R. K., PASSI, D., AGGARWAL, M., KAUR, G. 2016. Management of pediatric mandibular fractures using bioresorbable plating system – Efficacy, stability, and clinical outcomes: Our experiences and literature review. Journal of oral biology and craniofacial research 6, 101-106.

SINGH, V., SHARMA, B. & BHAGOL, A. 2011. Evaluating the applicability of a biodegradable osteosynthesis plating system in the management of zygomatico-maxillary complex fractures. Otolaryngol Head Neck Surg, 145, 924-9.

SUOMALAINEN, P., JÄRVELÄ, T., PAAKKALA, A., KANNUS, P. & JÄRVINEN, M. 2012. Double-bundle versus single-bundle anterior cruciate ligament reconstruction: a prospective randomized study with 5-year results. Am J Sports Med, 40, 1511-8.

SUOMALAINEN, P., KIEKARA, T., MOISALA, A. S., PAAKKALA, A., KANNUS, P. & JÄRVELÄ, T. 2014. J Sports Med, 5, 197-203.

SVERZUT, C. E., KATO, R. B., ROSA, A. L., TRIVELLATO, A. E., SVERZUT, A. T., DA SILVEIRA, K. M. & DE OLIVEIRA, P. T. 2012. Comparative study of bone repair in mandibular body osteotomy between metallic and absorbable 2.0 mm internal fixation systems. Histological and histometric analysis in dogs: a pilot study. Int J Oral Maxillofac Surg, 41, 1361-8.

TIRKKONEN, L., HAIMI, S., HUTTUNEN, S., WOLFF, J., PIRHONEN, E., SANDOR, G. K. & MIETTINEN, S. 2013. Osteogenic medium is superior to growth factors in differentiation of human adipose stem cells towards bone-forming cells in 3D culture. Eur Cell Mater, 25, 144-58.

TOMASINO, A., GEBHARD, H., PARIKH, K., WESS, C. & HARTL, R. 2009. Bioabsorbable instrumentation for single-level cervical degenerative disc disease: a radiological and clinical outcome study. J Neurosurg Spine, 11, 529-37.

TUNCER, S., YAVUZER, R., KANDAL, S., DEMIR, Y. H., OZMEN, S., LATIFOGLU, O. & ATABAY, K. 2007. Reconstruction of traumatic orbital floor fractures with resorbable mesh plate. J Craniofac Surg, 18, 598-605.

TURVEY, T. A., PROFFIT, W. P. & PHILLIPS, C. 2011. Biodegradable fixation for craniomaxillofacial surgery: a 10-year experience involving 761 operations and 745 patients. Int J Oral Maxillofac Surg, 40, 244-9.

VÄÄNÄNEN, P., NURMI, J. T., LAPPALAINEN, R. & JANK, S. 2009. Fixation properties of a biodegradable “free-form” osteosynthesis plate with screws with cut-off screw heads: biomechanical evaluation over 26 weeks. Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 107, 462-8.

VÄÄNÄNEN, P., PAJAMÄKI, I., PAAKKALA, A., NURMI, J. T., PAJAMÄKI J. 2010. The use of a biodegradable mesh plate to augment grafting of an acetabular defect: Laboratory investigation and clinical pilot study. J Bone Joint Surg Br. 2010 Jan;92(1):179-85.

VAZQUEZ-MORALES, D. E., DYALRAM-SILVERBERG, D., LAZOW, S. K. & BERGER, J. R. 2013. Treatment of mandible fractures using resorbable plates with a mean of 3 weeks maxillomandibular fixation: a prospective study. Oral Surg Oral Med Oral Pathol Oral Radiol, 115, 25-8.

WEBER, A. E., DELOS, D., OLTEAN, H. N., VADASDI, K., CAVANAUGH, J., POTTER, H. G., RODEO, S. A. 2015. Tibial and Femoral Tunnel Changes After ACL Reconstruction, The American Journal of Sports Medicine. Vol. 43, No. 5.

YANG, L., XU, M., JIN, X., XU, J., LU, J., ZHANG, C., LI, S. & TENG, L. 2014. Skeletal stability of bioresorbable fixation in orthognathic surgery: a systemic review. J Cranio-Maxillo-Fac Surg 42:e176-81.

YANG, Y., ZHOU, X., ZHANG, M., ZHOU, Y., WANG, B. & YUAN, C. 2019. Lateral wall osteotomy combined with embedded biodegradable implants for displaced intra-articular calcaneal fractures. Journal of Orthopedic Surgery and Research 14:74.

YOU, J. P., KIM, D. W., JEON, B. J., JEONG, S. H., HAN, S. K., DHONG, E. S. & KIM, W. K. 2013. Two-Year Follow-up on the Use of Absorbable Mesh Plates in the Treatment of Medial Orbital Wall Fractures. Arch Plast Surg, 40, 728-34.

YU, S. H. & BLOOMQUIST, D. Randomized Prospective Clinical Trial on Use of Resorbable Screws in Fixating Bilateral Sagittal Split Osteotomies for Mandibular Advancement. 95th Annual Meeting, Scientific Sessions and Exhibition in conjunction with the british Association of Oral and Maxxillofacial Surgeons, Orange County Convention Centre West, 2013, Orlando, FL.

YU, S. & BLOOMQUIST, D. 2014. Can resorbable screws effectively be used in fixating bilateral sagittal split osteotomies for mandibular advancement? A randomized controlled trail. J Oral Maxillofac Surg 72:2273-7.

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Version 8: 10/2019