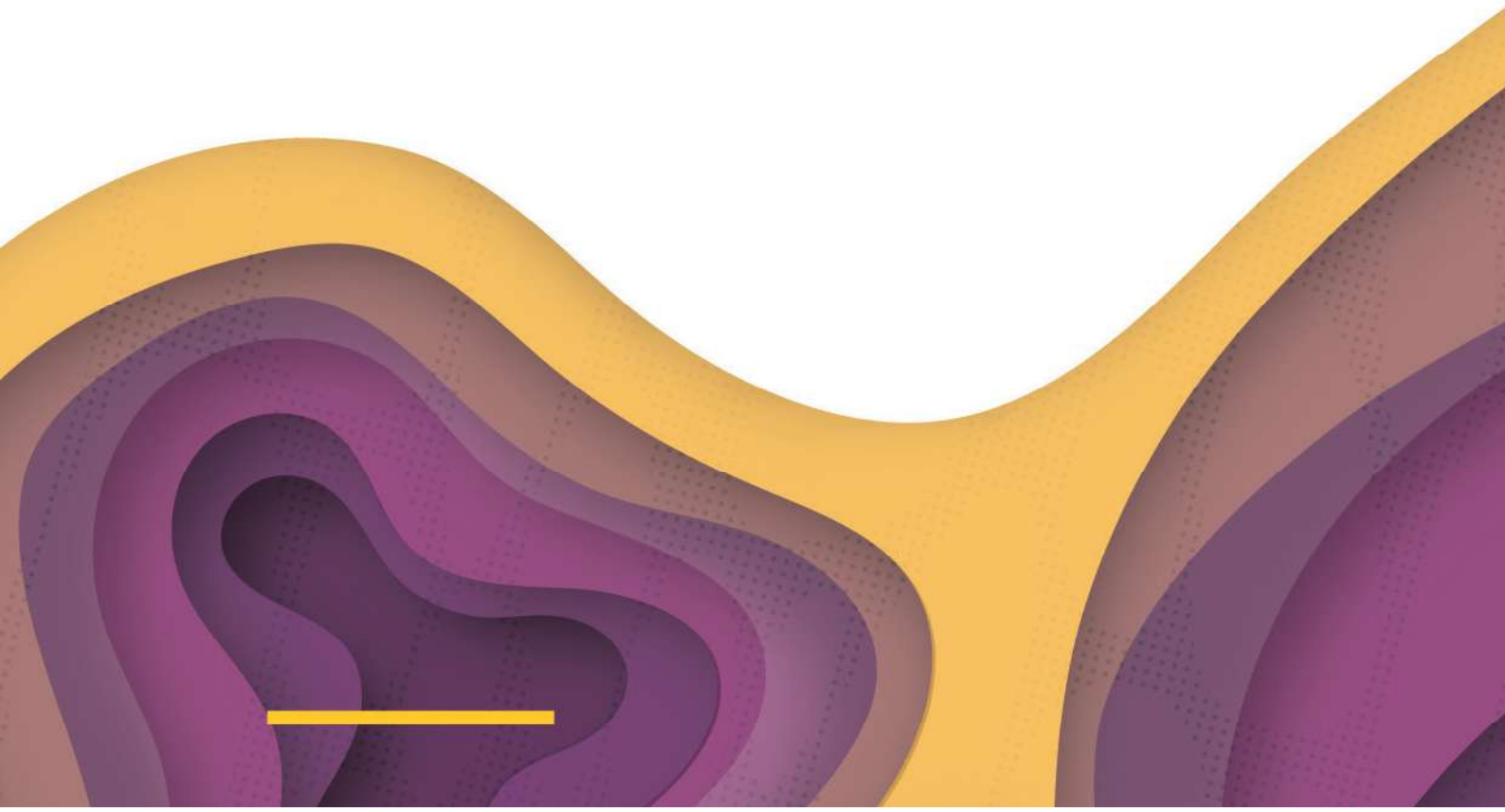
COLLAPAT® II

HAEMOSTATIC BONE SUBSTITUTE



FORM AND COMPOSITION

COLLAPAT® II

Haemostatic bone substitute biomaterial in a sponge form

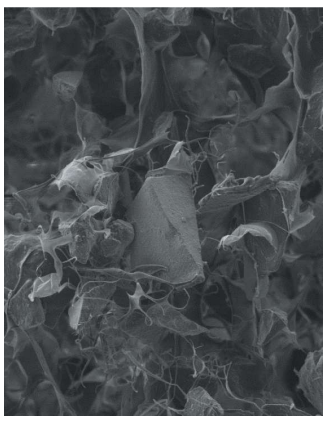
Composed of a collagen structure in which ceramised hydroxyapatite granules are dispersed.

- The granules of hydroxyapatite give the material its osteoconductive properties.
- **Hydroxyapatite** is the major mineral component of dental enamel, dentin and bone and is slowly resorbed[1].
- The **collagen** gives COLLAPAT® II its haemostatic power and is completely resorbable in a few weeks[2].
- The collagen is extracted from bovine dermis skins.
- Collagen extraction process fully integrated into the manufacturing plant in France (Chaponost, near Lyon).

The **manufacturing procedure** comprises stages recognised to inactivate viruses and non-conventional transmissible agents such as Prions. These treatments make it possible to ensure maximum microbiological safety for COLLAPAT® II, in particular in respect to the agent responsible for BSE.



The sponge available in 3 sizes



The collapat surface, MEB 100 μm

The collagen allows bone cells to migrate in the bone substitute by boosting bone tissue regeneration[1]. The newly formed bone tissue (immature tissue) will transform into mature bone tissue in a few weeks. The substitute is completely colonized by healthy tissue via intensive bone regeneration, and the collagen matrix is replaced by newly synthesized bone.

INDICATIONS



In orthopaedics

COLLAPAT® II is used to fill various types of bone defects:

- After extracting cortico-spongoid bone fragments.
- After tumour resection.
- In revision prosthesis.
- In surgical spondylodesis.
- In cases of pseudarthrosis.
- For certain fractures treated with osteosynthesis.



In maxillo-facial surgery and odonto-stomatology

COLLAPAT® II is also used for filling bone lesions in maxillofacial surgery and odonto-stomatology

- After removal of wisdom teeth or impacted cupsids.
- Filling for a sinus grafts.
- Restoration of bone stock following avulsion, trauma or tumours prior to fitting of implants.

EXAMPLES OF UTILIZATIONS

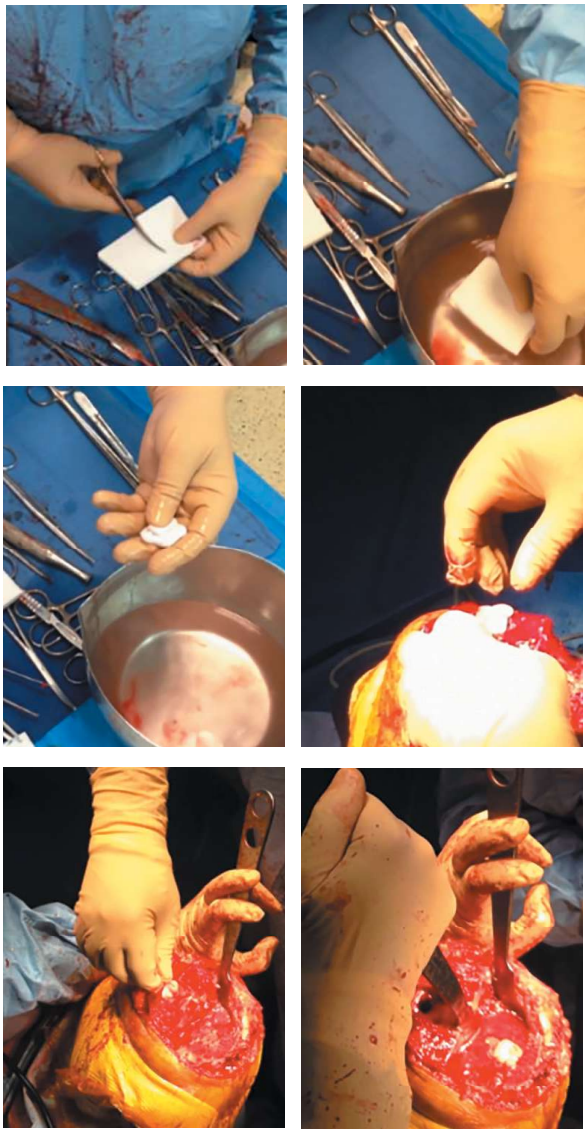
Specific utilizations are referred in the clinical data (page 8 and onwards)

- **Spinal surgery,**
  - In cervical surgery: alone inside cervical fusion cage.
  - In lumbar surgery: mixed with autograft and in contact with osteosynthesis material.
- **Foot surgery,** in the treatment of **Hallux valgus:** to fill the defect created by the osteotomy, then to fill the defect after the removal of the screws.
- **Knee and Hip in total prosthesis,** between the sharpened bone and the prosthesis.
- **Knee in ligamentoplasty:** to fill the bone graft harvesting sites and the entry to the tibial tunnel.

1 - Bone substitutes in orthopaedic surgery: from basic science to clinical practice, Campana & Coll, 2014
2 - Internal preclinical data

SURGICAL PROCESS

- COLLAPAT® II must be used in perfect sterile operating conditions after adequate preparation of the site to be treated.
- COLLAPAT® II can be cut, using surgical scissors, to the desired dimensions to facilitate its application. After being wet with tissue fluids, antibiotics or saline solution, COLLAPAT® II becomes soft and paste-like, which will ensure good filling of the cavity to be filled.
- Draining is strongly recommended but the drains must not be in direct contact with COLLAPAT® II. Rinsing of the implanted area is to be avoided.
- COLLAPAT® II is not designed to be removed except in the case of eventual post-surgical infection.
- In the case of widespread and very deep bone lesions or segment defects of more than 1 to 2 cm, autologous bone shavings or PRP (Platelet Rich Plasma) should be combined with COLLAPAT® II.
- Bone instabilities require supporting osteosynthesis.



Example Surgical procedure steps in Total Knee replacement

Precautions for use must be taken as follow

- COLLAPAT® II presents no shape stability or resistance to constraints. It therefore cannot be used for losses of instable bone substance, only in association with supporting osteosynthesis.
- COLLAPAT® II should not be used in a dry form but must be impregnated before use. In regions with low bone regeneration, COLLAPAT® II alone is ineffective, but can be used in association with an autologous spongious tissue, PRP (Platelet Rich Plasma) and/or after injection of autologous bone marrow.
- An insufficient regeneration is possible in unfavourable cases, in particular in case of very important loss of substance, or in regions of weak bone regeneration. These cases can be avoided by strictly observing the indications and instructions for use.
- There is only limited experience with repeated use of COLLAPAT® II, so it is recommended to be careful, given the exogenous origin of collagen, source of possible allergic reactions.
- COLLAPAT® II should not be used in case of acute or chronic infection of the surgical site or in high dosage corticosteroids treatment.
- COLLAPAT® II should not be used in patients presenting:
  - Septicaemia,
  - Severe bone degeneration or major osteoporosis,
  - Osteomalacia,
  - Hyper-parathyroidism or severe hypercalcaemia.
- COLLAPAT® II should not be used in pregnant women.
- Use COLLAPAT® II immediately after opening the bag.
- Do not use COLLAPAT® II after the expiry date indicated on the package.
- Do not use COLLAPAT® II if the integrity of the bags is damaged.
- If COLLAPAT® II is cut to the desired size, the product remains must be eliminated.
- COLLAPAT® II must not be stored for later use following package opening which might lead to infection risks
- COLLAPAT® II is a single-use product, it must not be re-sterilised.
- Note that since collagen reducing its adhesive power of the methyl methacrylate cement, COLLAPAT II should not be applied to bone surfaces onto which prosthetic materials must be attached with this cement.

COLLAPAT®II BENEFITS



Osteoconductive: it is generally completely colonized by the healthy orthotopic tissue thanks to intensive bone regeneration.

Haemostatic effect on the bone surfaces that it covers and on the muscles that are partially freed and replaced during surgery, stopping bleeding in a few minutes[3].

Ready to use and **easy to handle, to mold and to trim**[4].

Hydrophilic: the matrix takes the consistency of a paste in contact with blood or tissue fluids.

Perfect fitting to the anatomic area[5].

The SYMATESE Collagen Technology Platform gives to COLLAPAT®II its specifications

- The complete process is integrated to ensure SAFETY, QUALITY and RELIABILITY.
- COLLAPAT® II has cellular affinities, for tissue reconstruction thanks to the preservation of the biochemical and biological qualities of collagen.
- COLLAPAT® II is perfectly biocompatible thanks to the know-how and mastery of SYMATESE in the extraction and purification process.
- The porous COLLAPAT® II three dimensional mineral structure enhance osteoblast differentiation and accelerate osteogenesis in the entire graft site[1].

  A customized cross-linking process allows maintaining the collagen structure while the patient's cells colonize the graft, and allows for the collagen resorption after bone replacement[2].

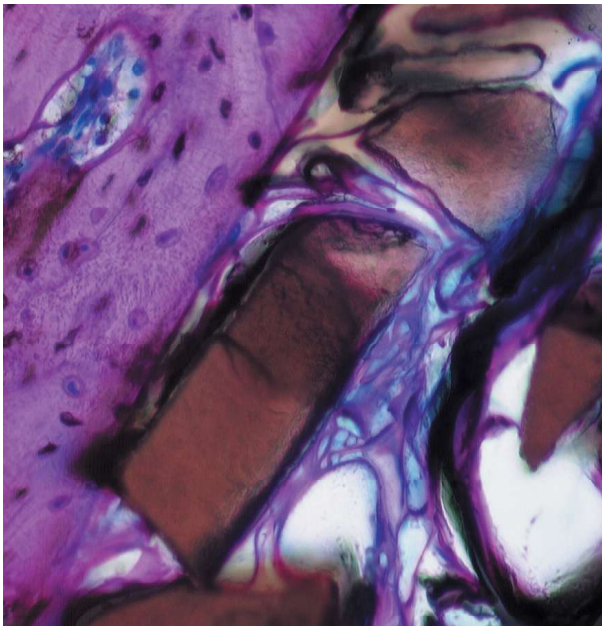
COLLAPAT® II offers

- **An alternative to autologous or allogenic grafts[3].**
- **Immediate and unlimited treatment availability unlike autologous bone. Avoids co-morbidities associated with autologous grafting.**

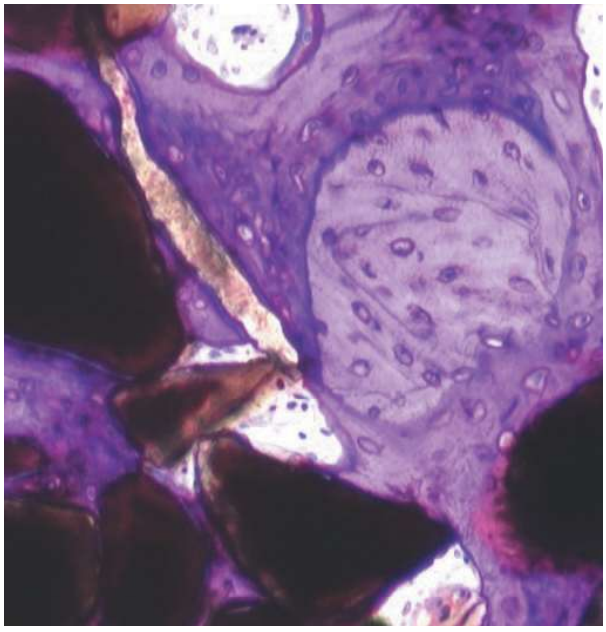
PRE-CLINICAL DATA[5]

SYMATESE manufactures Collagen Medical Device for more than 30 years. SYMATESE fulfills the ISO 13485: 2016 Quality System standards. The Collagen used for COLLAPAT® II is a Type I bovine.

The osteoconductive properties of COLLAPAT® II were demonstrated by means of a study on rabbits. COLLAPAT®. II was implanted in a cortico-cancellous defect 4.2 mm in diameter in the femoral site. The progression of bone regrowth was evaluated on histological sections from specimens included in resin magnified by a factor of 20 from T0 to T3 months.



The Hydroxyapatite granules are dispersed in the collagen matrix.



After 3 months, the bone reconstruction is complete and is characterized by a mature remodeled bone tissue

1 - Fernandez de Grado : «Some composite materials containing HA and collagen exist as well, and their combination enhances osteoblasts differentiation and accelerates osteogenesis.»

2 - SYMATESE internal data- COLLAPAT®II Clinical Evaluation Report.

3 - SYMATESE Preclinical data- Study 7513.

4- SYMATESE internal data - NOT 138.

5 - SYMATESE preclinical data - 6473 Study.

CLINICAL DATA

The product is available since 2002 and almost 100,000 patients have been treated with success by COLLAPAT® II

The addition of collagen to a ceramic structure can provide other additional advantages to surgical applications: shape control, spatial adaptation, increased particle and defect wall adhesion, and the capability to favor clot formation and stabilization[1]. COLLAPAT® II is performant, safe and easy to handle, the features satisfy physicians.

3 PMCF[2] studies have been performed.



Retrospective study on patient data assessing the safety and effectiveness of bone substitute COLLAPAT® II in orthopedic surgery and traumatology of

Hallux valgus

OBJECTIVES

To collect safety and performance data on COLLAPAT® II, in orthopedic foot surgery, in the treatment of Hallux valgus.

DEVICE USED/INDICATIONS AND CONDITIONS FOR USE

COLLAPAT® II in contact with screws (fixation material)
Indication: Foot surgery, treatment of Hallux valgus
38 COLLAPAT® II were implanted (reference: PAT35x6).

METHOD

Retrospective study on the use of COLLAPAT® II in foot surgery in the treatment of Hallux Valgus. The study includes all consecutively operated and implanted patients with COLLAPAT® II, from 08/01/2015 to 18/05/2015. Orthopedic Department, Polyclinique du Parc Drevon 21 000 Dijon, France.

SUBJECTS STUDIED
(number and population characteristics)

Number of patients: 38 (5 men and 33 women).

Average age: 56.1 years old (from 20 to 83 years old).

TREATMENT PROTOCOL:

In a first time, COLLAPAT® II is implanted to fill the defect created by the osteotomy. Then in a second surgery, COLLAPAT® II is used to fill the defect created by the removal of the screws.

The required amount has been defined for each patient. The structure and composition of COLLAPAT® II allow the surgeon to conform it exactly according to his needs. COLLAPAT® II is left in situ and complete colonization.

EVALUATION CRITERIA

► **Primary criterion:**

To assess overall safety of COLLAPAT® II in foot orthopedic surgery in the treatment of Hallux Valgus by analyzing number and severity of complications related to the device use.

► **Secondary criteria:**

- Collection of immediate postoperative complications, at one and until 12 months according to the surgeon's usual postoperative follow-up.
- Collection of postoperative complications occurring after 12 months according to the surgeon's usual postoperative follow-up.
- To assess the performance of bone substitute on ossification.
- To evaluate the reintervention rate at 12 months
- To evaluate rate of subjects followed at each time point according to the surgeon's usual postoperative follow-up.

CONCLUSION

In this retrospective study, COLLAPAT® II has been implanted to fill the defect consecutive to osteotomy and in a second time to fill the defect created by the removal of the screws. During and after both surgeries no complications related to COLLAPAT® II were observed.

After the first surgery (osteotomy), bone consolidation was acquired for 24.3% of patients at 3 months, 89% at 6 months and 100% for examined patiets at 12 months. Cases of delayed consolidation are related to external events that have a direct impact on the toe operated (fall, inappropriate behavior and torsion). After the second surgery, all defects were filled and consolidated. The patients reported no more discomfort and pain related to their pathology. This study confirms the safety and effectiveness of COLLAPAT® II in foot surgery of Hallux valgus.

1 - Bone substitutes in orthopaedic surgery: from basic science to clinical practice, Campana & Coll, 2014

2 - Post Market Clinical Follow-up, Not published – SYMATESE Internal reports

Immediate postoperative follow-up (during hospitalization) (N=38)

- No complication related to the use of COLLAPAT® II were observed

Postoperativefollow-up, from 1 to 3 months (N=37)

- Clinical examination: All patients had a good healing. 89.2% of subjects did not report pain.
- Radiological examination: bone consolidation is acquired for 9 subjects (24.3%) or ongoing for 25 subjects (67.6%) and delayed for 3 (8.1%). The cause of the delay is either mechanical (one fall and one twisting of the ankle) or behavioral (posture defect and active smoking).
- **Complications:** No complications related to the use of COLLAPAT® II were observed. However, 3 complications were reported: 2 edemas and one twisting of the ankle.

Postoperative follow-up, from 3 to 6 months (N=36)

- Clinical examination: All patients had a good metatarsal-phalangeal alignment. For 91.7% of patients the shape of the foot is good (disappearance of the exostosis). 2 patients had a small joint stiffness (no treatment). For 1 patient an erectus symptom is present (treated by tenolysis during the surgical revision for ablation of the screws of osteosynthesis).
- Radiological examination: bone consolidation is acquired for 32 subjects (89%) or almost acquired for 3 subjects (8.3) and not acquired for 1 active smoking subject (2.8%).
- Complications: No complications related to the use of COLLAPAT® II were observed.

Second surgery (removal of osteosynthesis screws, 2nd implantation of COLLAPAT® II to fill the defect caused by the screws) (N=25)

- Over the 25 patients prescribed for screws removal, 21 (84%) had the second surgery after 3 to 6 months. The mean duration between the 2 surgeries is about 4.5 months.

Postoperative follow-up, from 6 to 12 months (N=30)

- Non-reoperated patients (N=15):
- Clinical examination: For all patients, metatarsal-phalangeal alignment is satisfying and shape of the foot is good.
- Radiological examination: bone consolidation: 100% of patients (indication for screws removal)
- Complication: No complications related to the use of COLLAPAT® II were observed.
- Reoperated patients (N=15):

last follow-up for these patients.

- 93.3% of patients had a good healing.
- All patients did not report pain.
- 93.3% of patients did not present postoperative edema.
- All patient did not report functional disorder.
- No complications related to the use of COLLAPAT® II were observed.

Second surgery (N=15)

- Over the 15 patients prescribed for screws removal, 11 (73.3%) had the second surgery after 6 to 12 months. For these patients the mean duration between the 2 surgeries is about 9 months.

Post-reintervention follow-up, 6 to 12 months (N=9)

- All patients had a good healing.
- All patients did not report pain.
- All patients did not present postoperative edema.
- All patient did not report functional disorder.
- No complications related to the use of COLLAPAT II were observed.





Retrospective study on patient data assessing the safety and effectiveness of bone substitute COLLAPAT® II in orthopedic surgery and traumatology of

Spine

OBJECTIVES

To collect safety and performance data on COLLAPAT® II, in orthopedic and traumatology surgery of spine.

DEVICE USED/INDICATIONS AND CONDITIONS FOR USE

- **In cervical surgery:** COLLAPAT® II alone inside cervical fusion cage (osteosynthesis material).
- **In lumbar surgery:** COLLAPAT® II mixed with autograft and in contact with osteosynthesis material.

  Indication: Arthrodesis

  54 COLLAPAT® II were implanted (reference: PAT7x11)

METHOD

Retrospective study on the use of COLLAPAT® II in orthopedic surgery of the spine.

The study includes all consecutively operated and implanted patients with COLLAPAT® II, from 16/01/2015 to 03/09/2015.

Orthopedic Department, Clinique du Vert Coteau, 13012 Marseille, France.

SUBJECTS STUDIED

(number and population characteristics)

Number of patients: 43 (14 men and 29 women).

Average age: 54.5 years old (from 24.5 to 85.4 years old).

Treated area: 36 patients have a pathology of the lumbar spine (lumbar group) and 7 of the cervical spine (cervical group). Among the lumbar pathologies, 20 patients suffer from the sacro-lumbar region, 8 in the lumbar region and 8 in the dorso-lumbar region.

DIAGNOSIS	GLOBAL SPINE (N=43)	LUMBAR SPINE (N=36)	CERVICAL SPINE (N=7)
Degenerative disc disease	36 (83,72%)	31 (86,1%)	5 (71,4%)
Narrow lumbar canal	16 (37,21%)	14 (38,9%)	2 (28,6%)
Disc overflow	10 (23,26%)	7 (19,4%)	3 (42,9%)
Herniated disc	19 (44,19%)	14 (38,9%)	5 (71,4%)
Spondylolisthesis	14 (32,56%)	14 (38,9%)	0 (0,0%)
Degenerative kyphosis	16 (37,21%)	18 (50,0%)	3 (42,9%)
Other	16 (37,21%)	14 (38,9%)	2 (28,6%)

TREATMENT PROTOCOL

- In cervical spine surgery, COLLAPAT® II is used alone and placed into the inter-somatic cage to merge the vertebrae at the level of their vertebral body. One COLLAPAT® II is used per patient to fill the inter-somatic cage.
- In lumbar spine surgery, COLLAPAT® II is cut and combined with autologous graft to be implanted between the vertebrae (posterolateral graft) in order to form a bone bridge. 25 and 11 patients received respectively one and two COLLAPAT® II in combination with autologous graft. The mix is placed laterally outside the 2 stems (arthrodesis). The required amount of COLLAPAT® II has been defined by the surgeon for each patient depending on the amount of autologous graft sampled and the size of the arthrodesis to achieve.
  On average 5.8 [3-8] vertebral stages are merged by arthrodesis when two COLLAPAT® II are used.

COLLAPAT® II is left in situ until complete colonization.

EVALUATION CRITERIA

- **Primary criterion:**
  To assess overall safety of COLLAPAT® II in orthopedic surgery of the spine by analyzing number and severity of complications related to the device use.
- **Secondary criteria:**
  - Collection of immediate postoperative complications, at one and until 12 months according to the surgeon's usual postoperative follow-up.
  - Collection of postoperative complications occurring after 12 months according to the surgeon's usual postoperative follow-up.
  - To assess the performance of bone substitute on ossification.
  - To evaluate the reintervention rate at 12 months.
  - To evaluate rate of subjects followed at each time point according to the surgeon's usual postoperative follow-up.

CONCLUSION

In this retrospective study, COLLAPAT® II has been used to merge vertebrae (spondylodesis) and thus stabilize the degenerations of the vertebral column. COLLAPAT® II has been used alone in cervical surgery and combined with autologous graft in lumbar surgery. At all follow-up visits, no complications related to the use of COLLAPAT® II were reported. The performance was assessed radiologically, in all patients the bone consolidation of arthrodesis was confirmed (100% at 12 months) and absence of pseudo arthritis signs was noted.
This study confirms the safety and effectiveness of COLLAPAT® II in cervical (cervical anterior arthrodesis – intersomatic arthrodesis) and lumbar (posterior vertebral arthrodesis) spine surgeries.

Immediate postoperative follow-up (during hospitalization) (N=43)

- No complication related to the use of COLLAPAT® II were observed.

Early postoperative follow-up, at one month on average (N=43)

- **Clinical examination:** All patients had a good healing. Neither signs of infection nor inflammation. No complication related to the use of COLLAPAT® II were observed.
- **Radiological examination:**
- For all patients, osteosynthesis material is in place as well as intersomatic cage (for cervical group).
- The bone merge is not assessable at this time point.

Late postoperative follow-up n°1, at 6 months on average (N=40)

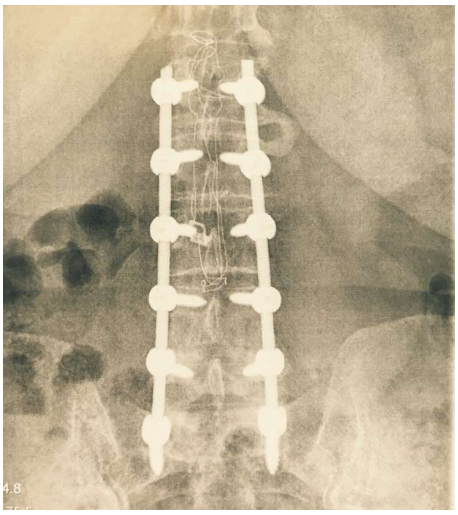
- **Clinical examination:** Neither signs of infection nor inflammation. No complications related to the use of COLLAPAT® II were observed.
- **Radiological examination:**
- **Lumbar group:** 21% of patients had a good consolidation of arthrodesis, ongoing consolidation for 79% of patients.
- **Cervical group:** 33.3% of patients had a good vertebrae merge, ongoing merge for 66.7% of patients
- In both groups, no patient presented signs of pseudo arthritis.

Late postoperative follow-up n°2, at 12 months on average (N=28)

- **Clinical examination:** No complication related to the use of COLLAPAT II were observed
- **Radiological examination:**
- In both groups, all patients had a good vertebrae merge.
- In both groups, no patient present signs of pseudo arthritis.

postoperative follow-up n°3, at 21 months on average (N=18)

- **Clinical examination:** No complication related to the use of COLLAPAT® II were observed.
- **Radiological examination:**
- In both groups, all patients had a good vertebrae merge.
- In both groups, no patient present signs of pseudo arthritis.





Retrospective study on patient data assessing the safety and effectiveness of bone substitute COLLAPAT® II in orthopedic surgery and traumatology of

Knee and Hip

OBJECTIVES

To collect safety and performance data on COLLAPAT® II, in orthopedic and traumatology surgery of knee and hip.

DEVICE USED/INDICATIONS AND CONDITIONS FOR USE

COLLAPAT® II is used in combination with non-cemented prosthesis. It is implanted between the sharpened bone and the prosthesis.

Indication: Total prosthesis of the knee / hip

36 COLLAPAT® II were implanted (reference: PAT7x11).

METHOD

Retrospective study on the use of COLLAPAT® II in orthopedic surgery of the knee and hip.

The study includes all consecutively operated and implanted patients with COLLAPAT® II, from 19/08/2015 to 06/07/2016.

Orthopedic department, Centre hospitalier Robert Morlevat 21140 Semur-en-Auxois, France.

SUBJECTS STUDIED

(number and population characteristics)

Number of patients: 36 (15 men and 21 women)

Average age: 75 years old (from 48.9 to 89.6 years old)

Treated area: 6 patients have pathology of the knee (knee group) and 30 of the hip (hip group).

DIAGNOSIS	GLOBAL (N=36)	HIP (N=30)	KNEE (N=6)
Pain	32 (88,9%)	26 (86,7%)	6 (100%)
Arthritis	33 (91,7%)	27 (90,0%)	6 (100%)
Necrosis	2 (5,6%)	2 (6,7%)	0 (0%)
Fracture	6 (16,7%)	6 (20,0%)	N/A
Other	11 (30,6%)	9 (30,0%)	2 (33,3%)

TREATMENT PROTOCOL

- **Total hip prosthesis:** COLLAPAT® II is used to line the bleeding subchondral bone to ensure the bone-cup connection and to control bone bleeding.
- **Total knee prosthesis:** COLLAPAT® II is placed in between the bleeding cut bone and the ceramic covered prosthesis. COLLAPAT® II guarantees bone-prosthesis connection and controls bone bleeding.

COLLAPAT® II is left in situ until complete colonization.

EVALUATION CRITERIA

- **Primary criterion:**

  To assess overall safety of COLLAPAT® II in orthopedic surgery of the knee and hip by analyzing number and severity of complications related to the device use.
- **Secondary criteria:**
  - Collection of immediate postoperative complications, at one and until 12 months according to the surgeon's usual postoperative follow-up.
  - Collection of postoperative complications occurring after 12 months according to the surgeon's usual postoperative follow-up.
  - To assess the performance of bone substitute on ossification.
  - To evaluate the reintervention rate at 12 months.
  - To evaluate rate of subjects followed at each time point according to the surgeon's usual postoperative follow-up.

CONCLUSION

In this retrospective study, COLLAPAT® II has been used to integrate and stabilize non-cemented prosthesis. No complications related to the use of COLLAPAT® II were observed throughout the follow-up period. Mobility was good for all patients. At 6 months on average, bone consolidation was acquired for all patients without signs of loosening, dislocation or pseudo arthritis.

This study confirms the safety and effectiveness of COLLAPAT® II in knee and hip surgeries (non-cemented total prosthesis).

Immediate postoperative follow-up (during hospitalization) (N=36)

- No complication related to the use of COLLAPAT® II were observed.

Postoperative follow-up n°1, at 1.5 month on average (N=33)

- **Clinical examination:** All patients had a good healing without signs of infection, inflammation or pain.
- No complications related to the use of COLLAPAT® II were observed.
- **Implantation performance:** Good mobility for 32 patients. The last patient also presented good mobility but with slight lameness.
- **Radiological examination:** bone consolidation acquired or ongoing for all patients.

Late postoperative follow-up n°2, at 6 months on average (N=16)

- **Clinical examination:** All patients had a good healing without signs of infection or inflammation. One patient treated for total knee prosthesis reported pain (amyotrophic persistence of the quadriceps).
- No complications related to the use of COLLAPAT® II were observed.
- **Implantation performance:** Good mobility for all patients.
- **Radiological examination:** bone consolidation acquired for all patients.

Late postoperative follow-up n°3, at 12 months on average (N=12)

- **Clinical examination:** Neither signs of infection nor inflammation. One patient treated for total knee prosthesis reported pain (non-arthritic residual pain of neurological origin).
- No complications related to the use of COLLAPAT® II were observed.
- **Radiological examination:** bone consolidation acquired for all patients, no signs of loosening, dislocation or pseudo arthritis.



MORE CLINICAL EXPERIENCES

with COLLAPAT® II reported by practitioners to SYMATESE



Effect of COLLAPAT® II, 5 years after market launch – Birbeau's case series.

Orthopedic surgery - Knee ligamentoplasty

OBJECTIVES

To study data on COLLAPAT® II to check that 25 years after its predecessor, COLLAPAT® II remains a bone substitute of choice. Effect of COLLAPAT® II 5 years after market launch and Comparison with data on first generation COLLAPAT® made by OSTEO in the 1980s then by STYKER in 2000.

DEVICE USED/INDICATIONS AND CONDITIONS FOR USE

COLLAPAT® II alone, no combination with marrow or an autograft or allograft. Orthopedic surgery – Knee ligamentoplasty using Kenneth-Jones technic.

TYPE OF STUDY

Prospective case series, one center.

CENTER(S)

Clinique Claude Bernard, 95120 Ermont, France. Doctor François Birbeau (Orthopedic physician), Doctor Laurent Fauroux (orthopedic surgeon), Doctor Chaduteau (Sports physician).

RANDOMIZATION WITH METHOD DESCRIPTION

Study of bone regeneration obtained during COLLAPAT® II application in a homogeneous series of 100 Kenneth-Jones operations all by the same surgeon and having systematically used a COLLAPAT® II sponge to fill the tibial and patellar graft harvesting sites and the tibial tunnel. The results were compared with a prior series of 100 Kenneth-Jones operations that did not use bone substitutes.

SUBJECTS STUDIED (number and population characteristics)

Number of patients: 100 cases: 88 men and 12 women.
Average age: 24 years and 5 months.
Analysis: 100 cases were analyzed.

TREATMENT PROTOCOL

Anterior incision about 10 cm long. Harvesting of a bone-patellar tendon bone graft, then using arthroscopy, tunnels made using the Linvatec kit. The Kenneth-Jones graft was fixed under isometric tension by two resorbable interference screws. Bone graft harvesting sites and the entry to the tibial tunnel were filled with COLLAPAT® II sponge.
COLLAPAT® II is left in situ until complete colonization.

DIAGNOSIS AND PRINCIPAL INCLUSION CRITERION

Subjects have a Kenneth-Jones operation.

Classification of Kenneth-Jones interventions is:

- **T1:** Loss of substance with a bone continuity persistence e.i.Patellar outtake.
- **O:** CS The bone edging the cavity is cortico-spongious.
- **D: D-:** the distance between the filled point and the receiving bone does not exceed 10 mm.

COMPARABLE DEVICE

(or other comparable therapeutic strategy)

Indications and conditions of use. Comparison to 100 cases that did not receive COLLAPAT® II bone substitute.

MONITORING PERIOD

Evaluation at 2 years.

EVALUATION CRITERIA

Main criterion: New bone formation observed visually

Secondary criterion if need be: Analysis of side effects.

RESULTS

Removal day D4-D5. Immediate complications 1 phlebitis.

Full weightbearing without cane.

At D45: No mechanical complications.

One aseptic inflammation healed medically.

No infectious complication. One algodystrophy.

Full weightbearing without cane in 98% of cases.

Radiologic progress: Consolidation ongoing.

Receiving bone: discrete osteolysis.

Peripheral radiolucent line: 1 mm. Substitute showing start of bone matrix condensation (radiology).

At D180 :

- **Radiologic progress:**
  - Consolidation obtained and receiving bone redensified.
  - Peripheral radiolucent line disappeared.
  - Substitute showing bone condensation (radiology).
- **On postoperative bleeding:**
  - Series without COLLAPAT® II average for 2 suction drains (Redon): 350 mL and 3 hematomas had to be punctured in the operating theater.
  - Series with COLLAPAT® II average for 2 Redon drains: 80 mL no hematoma.

On the reconstruction of bone harvest areas:

- **Series without COLLAPAT® II:**
  - At 2 years 14% of patellar sections palpable and painful upon kneeling.
  - Risk of fracture with general harvesting or flat patella hence the importance of filling this defect.
  - In the upper tibial metaphysis in the series not grafted with COLLAPAT® II a fracture of the outer tibial plateau was noted 6 months after ACL reconstruction, probably due to fragility related to graft take and making the tibial tunnel.
- **Series with COLLAPAT® II:**
  - At 2 years 2% of patellar sections palpable and curiously painless. No tibial plateau fractures were observed.
  - The X-rays reveal that the patellar defect has been filled, but not the tibial tunnel defect.

CONCLUSION

The COLLAPAT® II bone substitute, which claims to have osteoconductive and hemostatic properties, has optimized the results of Kenneth-Jones type ACL reconstruction by reducing hematoma formation and accelerating healing at the graft harvest site, while also reducing the number of fractures after bone healing and limiting pain.



Case report in maxillofacial surgery:

Dental implant and Sinus lift

OBJECTIVES

Sinus elevation.

DEVICE USED/INDICATIONS AND CONDITIONS FOR USE

COLLAPAT® II (reference: PAT 35x6) with PRF membranes.

TYPE OF STUDY

Case report.

SUBJECTS STUDIED

(number and population characteristics)

42 years old female.

TREATMENT PROTOCOL

Filling bone defect with bone substitute COLLAPAT® II . COLLAPAT® II was cut and positioned between PRF membranes and sinus floor. Closure of the gingival flap by suture in single points.

CONCLUSION

COLLAPAT® II is effective and well tolerated in maxillofacial surgery for sinus lift. Two implants have been placed after bone consolidation (at least 6 months).

DURATION OF USE

COLLAPAT® II is left in situ and completely colonized and assimilated.

COMPARABLE DEVICE

(or other comparable therapeutic strategy)

Indications and conditions of use.

No comparator.

ASSESSMENT CRITERIA

New bone formation observed visually and potential side effects.

RESULTS

COLLAPAT® II was easy to use and manipulate. The implantation was satisfying. Two implants were placed successfully 6 months after grafting.









REFERENCES	SIZE	UNITS
PAT35X6	3.5 x 6 x 0.6 cm	1 unit per box
PAT7X11	7 x 11 x 0.6 cm	1 unit per box
PAT1X1X1	1 x 1 x 1 cm	5 units per box

- COLLAPAT® II is sterilized by irradiation at 25 kGy.
- COLLAPAT® II sponges are presented in a double light and moisture-proof packaging, in single boxes, one unit per box, except for the 1 x 1 x 1 cm form which is presented in boxes of five units.
- COLLAPAT® II should be stored at room temperature (+10°C to +30°C).
- COLLAPAT® II has obtained CE marked by the notified body G-MED n°0459 and is a Class III Medical Device made by SYMATESE - Chaponost – FRANCE.
- COLLAPAT® II is the result of a technological transfer of COLLAPAT which was marketed in 1980.

CE 0459

COLLAPAT® II



For more information or to place an order, please contact:

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