

# Evaluation of the TEKTONA® system designed to restore vertebral height in the treatment of vertebral fractures by compression

<b>Submission date</b> 13/04/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/06/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This is a post-market study to confirm the performance and safety of the TEKTONA system in the treatment of vertebral compression fractures. A compression fracture is usually defined as a vertebral bone in the spine that has decreased at least 15 to 20% in height due to fracture. The TEKTONA medical device reduces the vertebral fracture and allows the cement injection in the vertebra to consolidate it.

### Who can participate?

Patients aged 18 years and over with vertebral compression fracture

### What does the study involve?

The patient is screened during the preoperative visit. Those patients who are eligible for the study are invited to participate in the study. After reading the information letter, the patients should let their surgeon know if they agree/consent before any data collection. Clinical and radiographic data are collected at their preoperative, surgical, and postoperative clinical visits performed as the site standard of care.

### What are the possible benefit and risks of participating?

As an observational study, there is no benefit or risk for the patients participating in the study.

### Where is the study run from?

Spineart SA (Switzerland)

### When is the study starting and how long is it expected to run for?

January 2016 to December 2020

### Who is funding the study?

Spineart SA (Switzerland)

Who is the main contact?  
clinic@spineart.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
P61\_CLD001

## Study information

**Scientific Title**  
Evaluation of the safety and performance of the compression spinal fracture treatment system, TEKTONA® prospective study

**Acronym**  
TEKTONA® system

**Study objectives**  
The TEKTONA® system is designed to restore the vertebral height and reduce the angle of vertebral kyphosis, for the treatment of osteoporotic or osteopathic vertebral settlement fractures (FTV) Type A1 and A2 (a gap between fragments of less than 2 mm) and A3 in the MAGERL classification.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 26/04/2016, CPP Ile-de-France VI (Groupe Hospitalier Pitié-Salpêtrière, 47 Boulevard de l'Hôpital, 75013, Paris, France; +33 (0)1 42 16 16 83; cppidf6.salpetriere@yahoo.fr), ref: ID RCB 2016-A00150-51, CCTIRS # 16-640

## **Study design**

Post-market clinical follow-up (PMCF) prospective multicenter single-arm observational study

## **Primary study design**

Observational

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Vertebral compression fracture, stable type, without neurological deficit

## **Interventions**

Evaluation of qualitative and quantitative of pre-, peri- and post-operative data. Comparison between pre-and post-operative values provided by radiological parameters, pain medication, VAS, ODI and SF-12 scores. The risk assessment is determined by the rate of complications observed.

## **Intervention Type**

Device

## **Phase**

Phase IV

## **Drug/device/biological/vaccine name(s)**

TEKTONA®

## **Primary outcome(s)**

1. Risks are measured by the incidence of perioperative complications and safety reporting and post-operative risks (adverse events reporting, radiological assessments at 6, 12 and 24 months)
2. Restoration of vertebral height (mm) and reduction of kyphosis (Cobb Angle) at the level operated is measured by comparing radiological images pre-surgery, perioperative, immediate post-surgery, at 6-, 12- and 24-months post-surgery

## **Key secondary outcome(s)**

1. Volume of cement injected and cement distribution (vertebral and horizontal) is measured (in ml) at surgery
2. Effectiveness of the system is measured by the duration of post-operative hospitalization
3. Pain is evaluated by changes in the use of pain medication and the visual analogue score (VAS) score pre-surgery, immediate post-surgery, at 6-, 12- and 24-months post-surgery
4. Quality of life is measured using the SF-12 questionnaire preoperatively, immediate postoperatively and at 6, 12 and 24 months and time between intervention and back to work
5. Functional evaluation using Oswestry Disability Index (ODI) score preoperatively, immediate postoperatively and at 6, 12 and 24 months

## **Completion date**

07/12/2020

## Eligibility

### Key inclusion criteria

1. Aged 18 years or older
2. Presenting one or more three stable vertebral fractures at non-adjacent levels, fractures type A1.1, A1.2, A1.3, A2 (gap between fragments less than 2 mm) and A3.1, A3.2, A3.3 according to Magerl classification
3. Presenting vertebral traumatic fracture(s), due to high-energy trauma, or osteoporotic fall of one's own height
4. Able to understand the investigation protocol, agree with the investigation plan, and complete the necessary documents
5. Who voluntarily signed the informed consent form

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

37

### Key exclusion criteria

1. Anterior treatment with cyphoplasty at the fractured level
2. Unstable fractures of type B or C according to Magerl
3. Size of the pedicles incompatible with safe access to the instrument

### Date of first enrolment

22/11/2016

### Date of final enrolment

12/12/2018

## Locations

### Countries of recruitment

France

**Study participating centre**  
**Hopital La Pitié-Salpêtrière**  
Service de Chirurgie Orthopédique et Traumatologie  
47-83 Bd de l'Hôpital  
Paris  
France  
75651

**Study participating centre**  
**Hôpital Michallon**  
Service de Chirurgie Orthopédique et Traumatologie  
Grenoble  
France  
38043

**Study participating centre**  
**Hôpitaux Universitaires de Strasbourg**  
Service de Chirurgie du Rachis  
1, Place de L'Hôpital  
Strasbourg  
France  
67000

## **Sponsor information**

**Organisation**  
Spineart (Switzerland)

**ROR**  
<https://ror.org/05sz2c652>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Spineart SA

# Results and Publications

## Individual participant data (IPD) sharing plan

The dataset generated and analysed during the current study will be available upon request from clinic@spineart.com.

The type of data that will be shared: clinical data of the study

Dates of availability: up to 2035

Whether consent from participants was required and obtained: Yes

Comments on data anonymization: All subjects' data are pseudo-anonymized

Any ethical or legal restrictions: No restrictions

## IPD sharing plan summary

Available on request