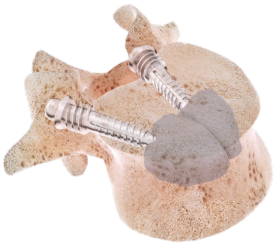
Safe Orthopaedics announces the publication of a biomechanical study on Sycamore



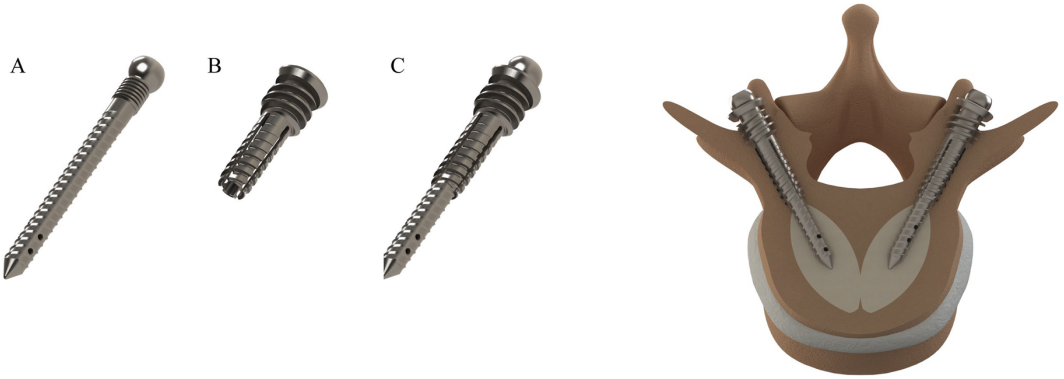
- Publication in the *Journal of Experimental Orthopaedics* of the results of the Sycamore biomechanical study
- Over 160 patients treated with Sycamore

Éragny-sur-Oise, Fleurieux sur l'Arbresle, France, le 07 août 2023 à 17h30 CET – Safe (FR001400F1V2 – ALSAF), french group specialized in the design, manufacturing and distribution of ready-to-use medical devices for Spine surgeries, especially safe for vertebral fracture treated in emergency, announces the publication of a biomechanical study of Sycamore and over 160 patients treated with Sycamore.

Publication of the results of the Sycamore biomechanical study in the Journal of Experimental Orthopaedics (https://jeo-esska.springeropen.com/articles/10.1186/s40634-023-00635-7)

Leaded by Professor Jean-Charles Le Huec, the study compares the biomechanical behavior of vertebrae treated by "Dowelplasty", a new surgical technique using a pedicle anchored device Sycamore (commercial name by Safe Orthopedics) with a traditional kyphoplasty system. The study is published in the Journal of Experimental Orthopedics.

Sycamore consists of (a) a cannulated titanium nail and (b) a titanium dowel directly anchored in the pedicle; (c) the cannulated nail is inserted and locked into the dowel, and the cement is injected through the nail.



Results:

In comparison with the Kyphoplasty, Sycamore shows a significant increase of the compression strength (373 N ; IC à 95% ; – 331 N versus – 1076 N for Sycamore).

Table 2 Failure load, energy at fracture, and stiffness, stratified by treatment group

	Dowelplasty (*n*=11)		Balloon kyphoplasty (*n* = 11)		Mean difference	(95%CI)	*p*-value**
	Mean ± SD	(95%CI)	Mean ± SD	(95%CI)			
Fracture load							
Pre-treatment (N)	2065 ± 854	(1492 –2639)	2256 ± 775	(1736 –2777)	-191	(-916 –534)	0.511
Post-treatment (N)	2291 ± 648	(1855 –2726)	2109 ± 612	(1698 –2520)	182	(-379 –743)	0.743
Net change (N)	225 ± 765	(-289 –740)	-147 ± 815	(-695 –400)	373	(-331 –1076)	0.375
p-value*	0.365		0.520				
Fracture energy							
Pre-treatment (Nmm)	2729 ± 1416	(1778 –3680)	3104 ± 1502	(2095 –4113)	-375	(-1673 –924)	0.430
Post-treatment (Nmm)	4199 ± 1421	(3245 –5154)	3819 ± 1343	(2917 –4722)	380	(-850 –1610)	0.577
Net change (Nmm)	1470 ± 1260	(624 –2317)	716 ± 1673	(-408 –1840)	755	(-563 –2072)	0.270
p-value*	0.007		0.123				
Stiffness							
Pre-treatment (N/mm)	1552 ± 607	(1144 –1960)	1743 ± 631	(1319 –2166)	-190	(-741 –360)	0.365
Post-treatment (N/mm)	1335 ± 396	(1069 –1601)	1180 ± 332	(957 –1403)	155	(-170 –480)	0.401
Net change (N/mm)	-217 ± 546	(-584 –150)	-562 ± 604	(-968 – -156)	345	(-167 –857)	0.401
p-value*	0.320		0.005				

Abbreviations: *SD* Standard deviation, *CI* Confidence interval

* *P*-values comparing pre- versus post-treatment using paired wilcoxon signed rank tests

** *P*-values comparing dowelplasty versus kyphoplasty using unpaired wilcoxon rank sum tests

Conclusions:

1- The treatment of a compression fracture with Sycamore allows a very significant increase in the resistance to load of the fractures compared to the pre-treatment state.

2 - Sycamore provides a greater improvement in load resistance and fracture displacement energy than balloon kyphoplasty, suggesting that Sycamore may be a good alternative for the treatment of vertebral compression fractures.

Sycamore provides greater improvement of the load resistance and fracture displacement energy compared to traditional kyphoplasty, suggesting that Sycamore is a good alternative for the treatment of vertebrae compression fractures.

Professor Jean-Charles Le Huec, user of the system confirms in clinical practice the good results obtained in the laboratory. With a follow-up of 2 years, the losses of corrections do not exceed 2.1° compared to the immediate postoperative results. This is truly remarkable compared to kyphoplasty and other systems on the market without pedicle anchorage where the cement can sink into the vertebral body, especially in cases of osteoporosis.

Pierre Dumouchel, Chairman and CEO de Safe Group comments « First of all, we would like to thank Professor Jean-Charles Le Huec and all the surgeons who contributed to the development and clinical follow-up of Sycamore, a unique and patented Safe Orthopedics technology for better management of patients with vertebral fractures. We have treated over 160 patients with our Sycamore technologies and are seeing very promising clinical results. Through recent listings in many French centers and international deployment, we are delighted to be able to benefit a large number of patients from the clinical benefits already observed and aim to accelerate the Safe Orthopaedics sales».

About Safe Group

Safe Group is a French medical technology group that brings together Safe Orthopaedics, a pioneer in ready-to-use technologies for spine pathologies, and Safe Medical (formerly LCI Medical), a medical device subcontractor for orthopedic surgeries. The group employs approximately 125 people.

Safe Orthopaedics develops and manufactures kits combining sterile implants and ready-to-use instruments, available at any time to the surgeon. These technologies are part of a minimally invasive approach aimed at reducing the risks of contamination and infection, in the interest of the patient and with a positive impact on hospitalization times and costs. Protected by 15 patent families, SteriSpine™ kits are CE marked and FDA approved. Safe Orthopaedics is headquartered in the Paris region (95610 Eragny-sur-Oise) and has subsidiaries in the United Kingdom, Germany, the United States, and the Lyon region (Fleurieux-sur-l'Arbresle).

For more information: http://www.safeorthopaedics.com/

Safe Medical produces implantable medical devices and ready-to-use instruments. It has an innovation center and two production sites in France (Fleurieux-sur-l'Arbresle, 69210) and in Tunisia, offering numerous industrial services: industrialization, machining, finishing and sterile packaging.

For more information: http://www.safemedical.fr/

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