Variable Fixation Locking Screw (VFLS®) Technology

Flexible at the right stage, always stable.

FAQs

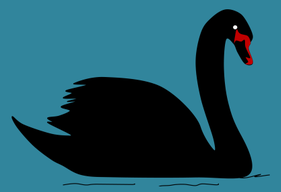
BIOMECH INNOVATIONS

- Why is a new technology important?
- What is VFLS® technology?
- VFLS® anatomy.
- What changes in the surgical technique?
- What increase in construct flexibility can be expected using Variable Fixation Locking Screws?
- What increase in interfragmentary movements can be expected using Variable Fixation Locking Screws?
- What is the effect on the callus forming in the fracture gap?
- The bone is an organ!
- The screw at the center.
- Why use VFLS®?
- Evidence about Variable Fixation in peer reviewed journals.
- How to get more information about Variable Fixation?

BIOMECH INNOVATIONS

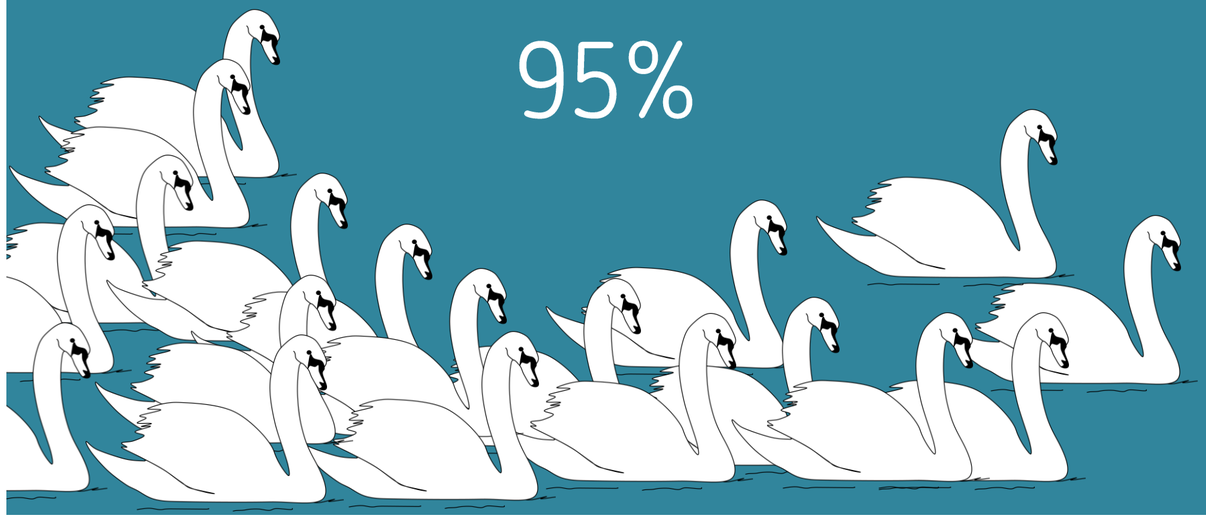
Today's screw technology is not enough for tomorrow.

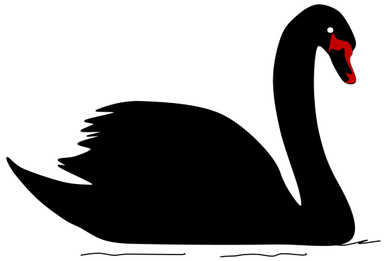
Estimated incidence of healing complications on fractures.



5% the "**black swan**" of osteosynthesis.

95%





Extremely unpredictable events having massive impacts on **patients** and on the **healthcare system**.

In working aged population the **5% experiencing poor healing** has been estimated to more than **double** the work losses and medical **costs** [1].

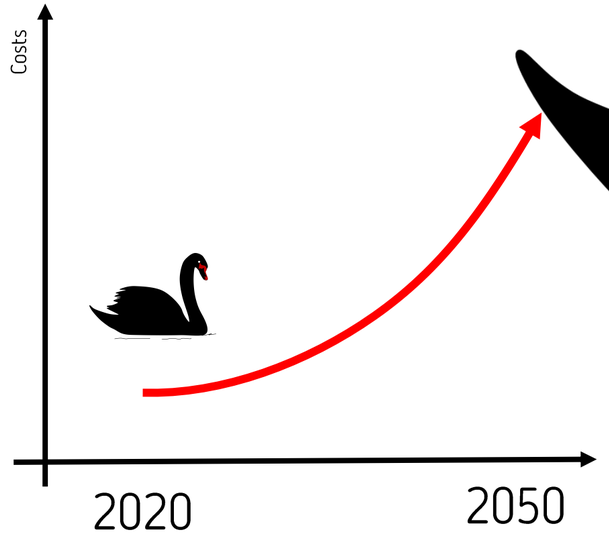
much longer treatment + high risk of further complications, like hardware failure, all the risks linked to additional surgeries, including infection and amputation.

BIOMECH INNOVATIONS

Today's screw technology is not enough for tomorrow.

Population growing and **aging** has produced an about **+30%** increase in the absolute count of fractures worldwide between 1990 and 2018 [2]. **This trend is not expected to change in the next three decades.**

Such societal problem requires an interdisciplinary and collegial approach to help policy makers determining how to maximize the effect of fracture prevention and treatment programs.

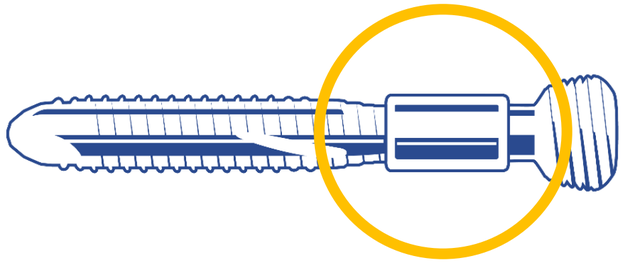


Projection on population aging suggests that the **cost and the societal burden** of complicated fracture cases **will not be sustainable** in the coming years [3-10].

We contribute optimizing the treatment **with a revolutionary technology.**

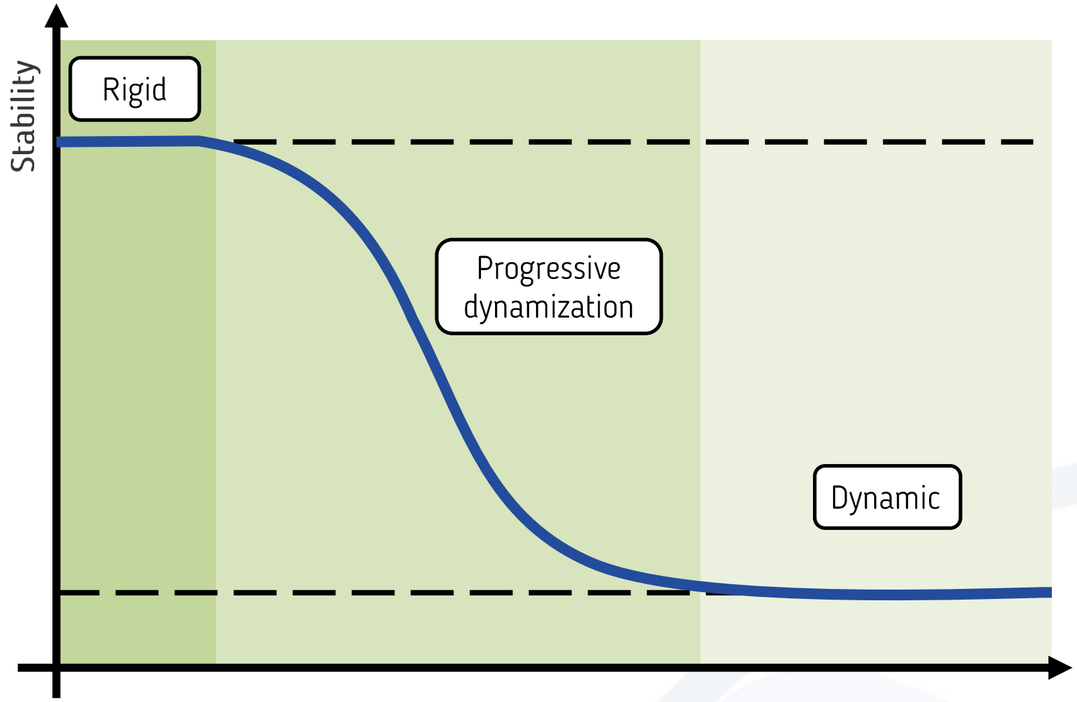
BIOMECH INNOVATIONS

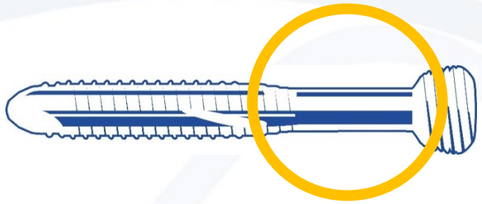
Natural transition from rigid to dynamic stability.

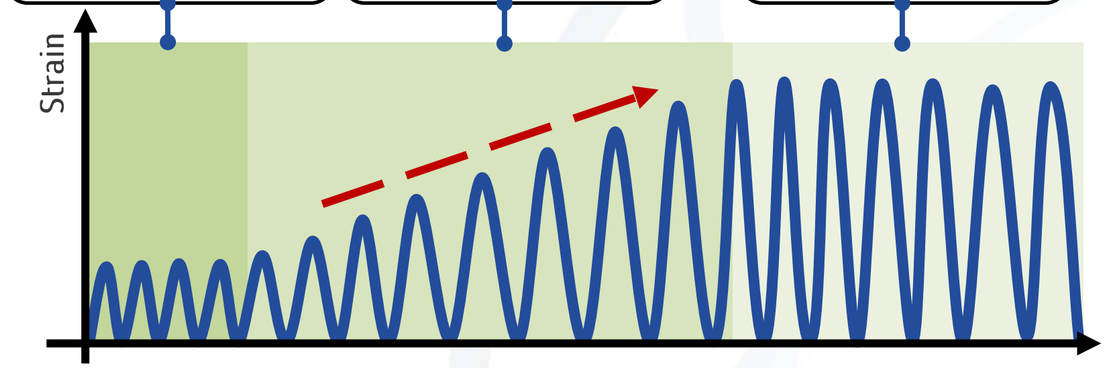


The **key** of Variable Fixation is the **advanced resorbable sleeve.**

Its degradation **leads to a progressive change** in fixation stability, **providing a progressive stimulation of the fracture gap.**





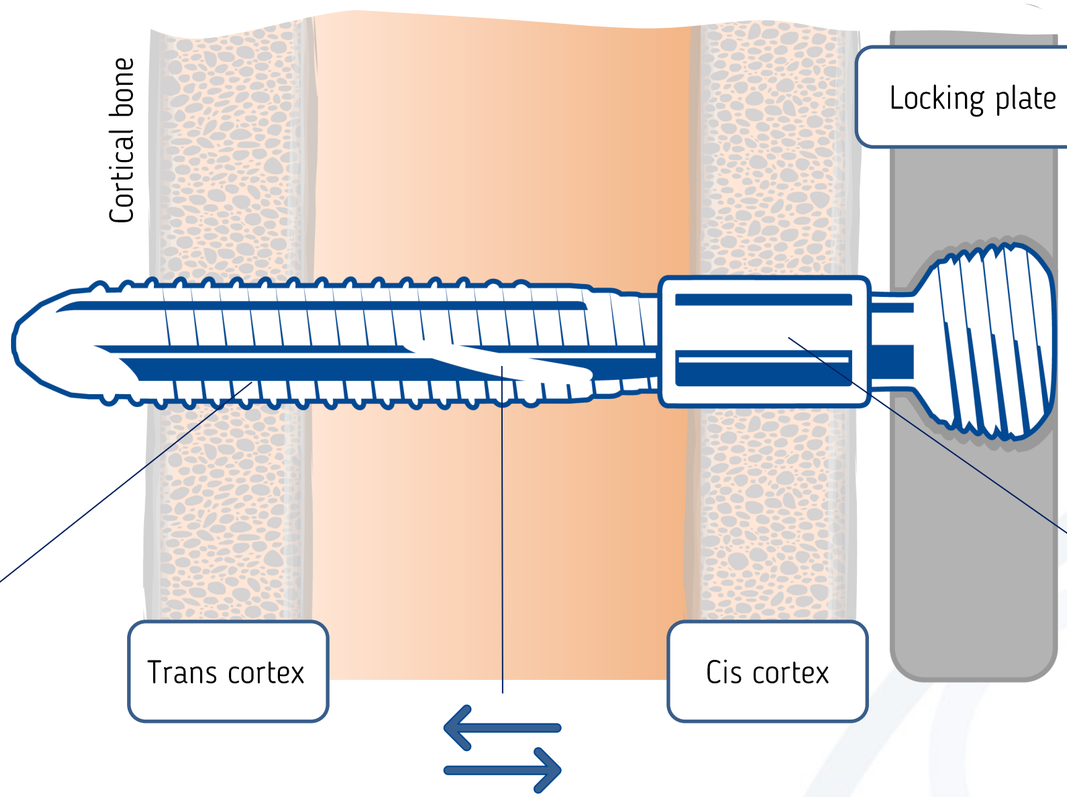


BIOMECH INNOVATIONS

Variable Fixation Locking Screw - VFLS®

Self-tapping tip

Cortical threads



Locking head

Degradable sleeve

Forward and backward cutter

As the screw advances, the cutter prepares in the cis cortex a **precise sitting for the sleeve**. The same tool features reverse threaded cutting edges designed to engage and cut the cis cortex allowing screw removal at the end of treatment.

BIOMECH INNOVATIONS

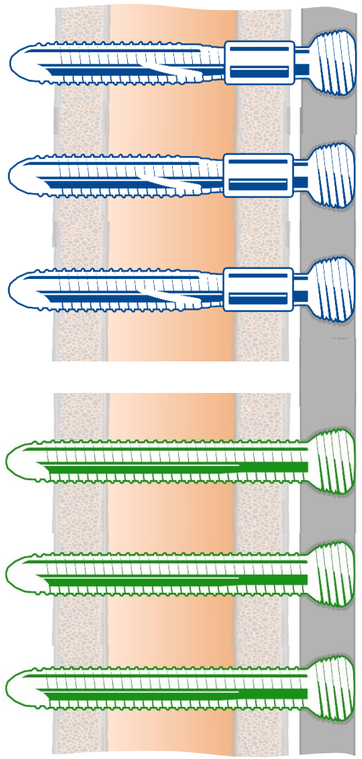
Same surgical technique.

Choose one of the following two options.

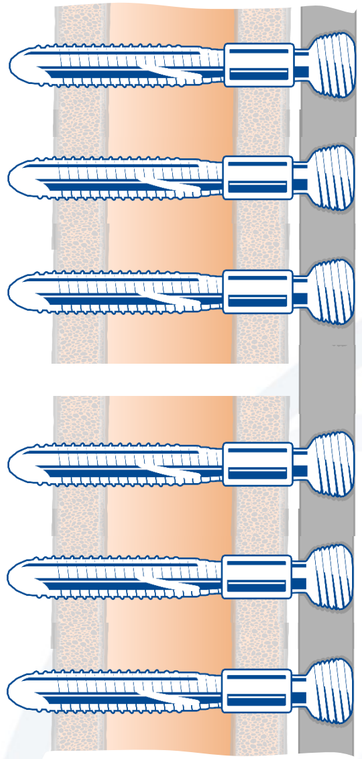
Variable Fixation
on one cortical bone segment

and

standard locking
on the other cortical bone segment.



OR



Variable Fixation
on both cortical bone segments.

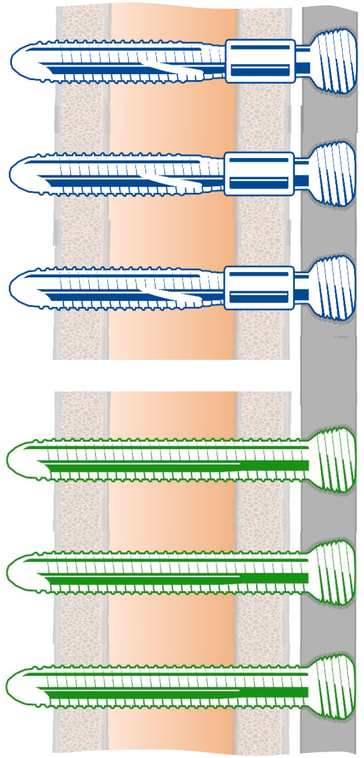
Do not mix VFLS® with other screws in the same cortical bone segment.

BIOMECH INNOVATIONS

With an intact sleeve, Variable Fixation provides the **same construct flexibility** provided by standard locking fixation [11].

+15%

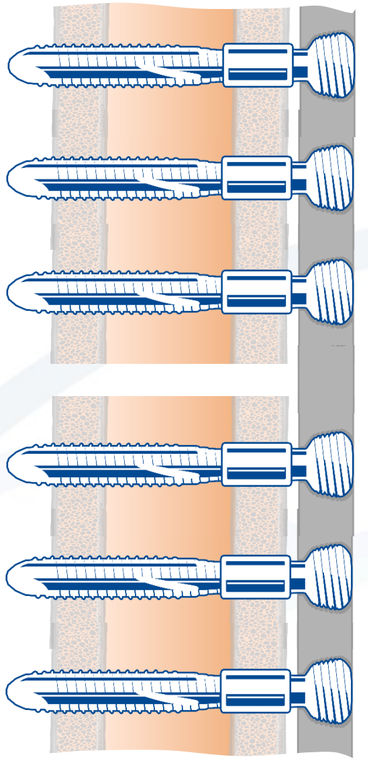
construct flexibility, at complete resorption of the sleeve.



Using Variable Fixation [11] on **one bone segment**.

+30%

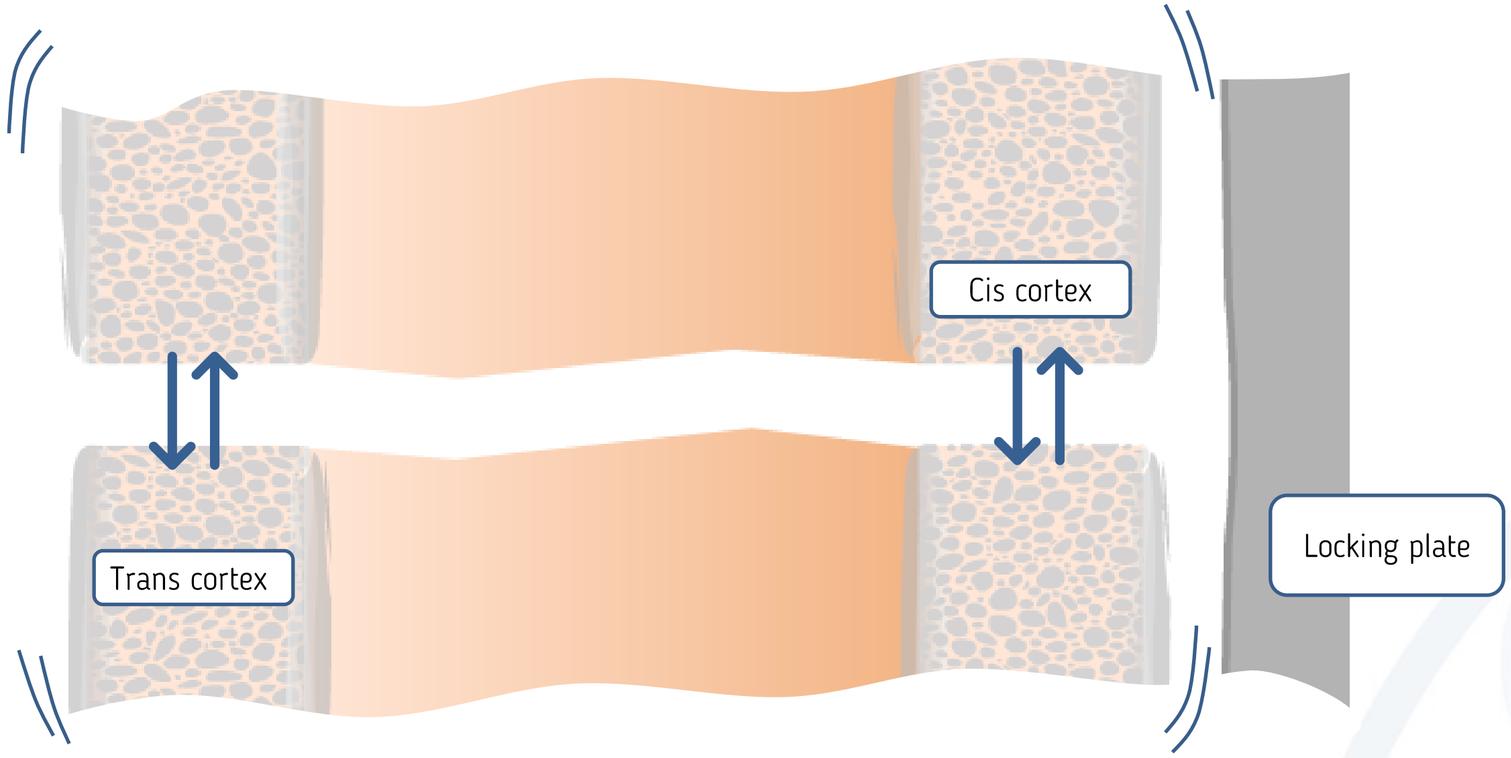
construct flexibility, at complete resorption of the sleeve.



Using Variable Fixation [11] on **both bone segments**.

BIOMECH INNOVATIONS

The **gradual change in displacement trajectory** of bone fragments leads [11] to …



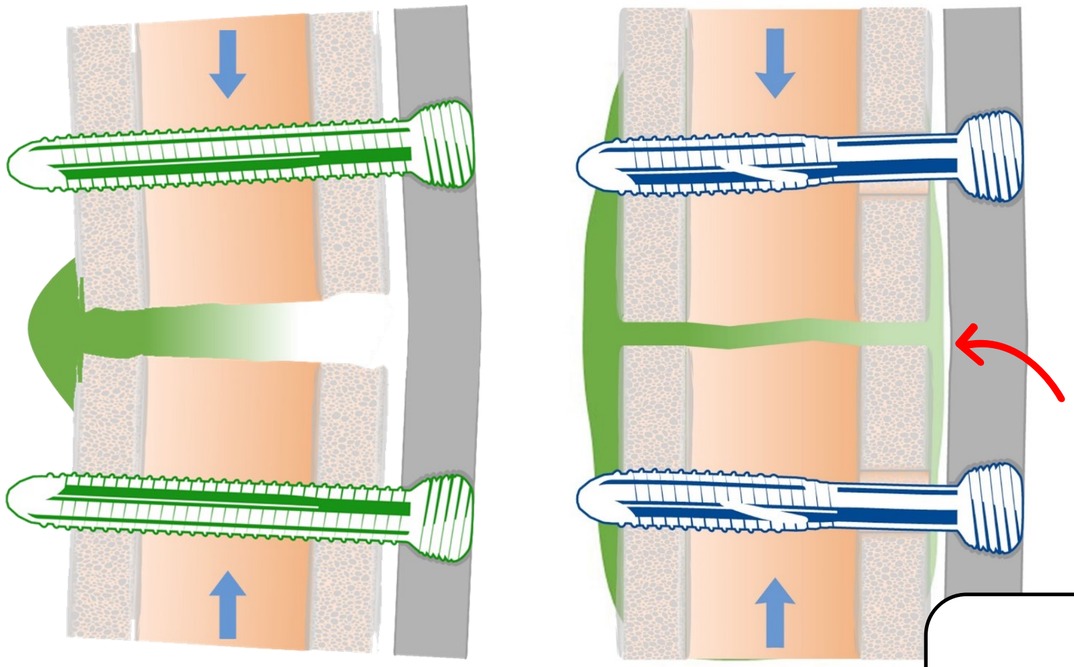
Up to **+37%**.

Up to **+125%**.

… a **gradual and different increase in cis and trans cortices** interfragmentary displacements.

BIOMECH INNOVATIONS

Compared to standard locking, Variable Fixation technology leads to the deposition of a **much larger and better distributed** bone callus [12].



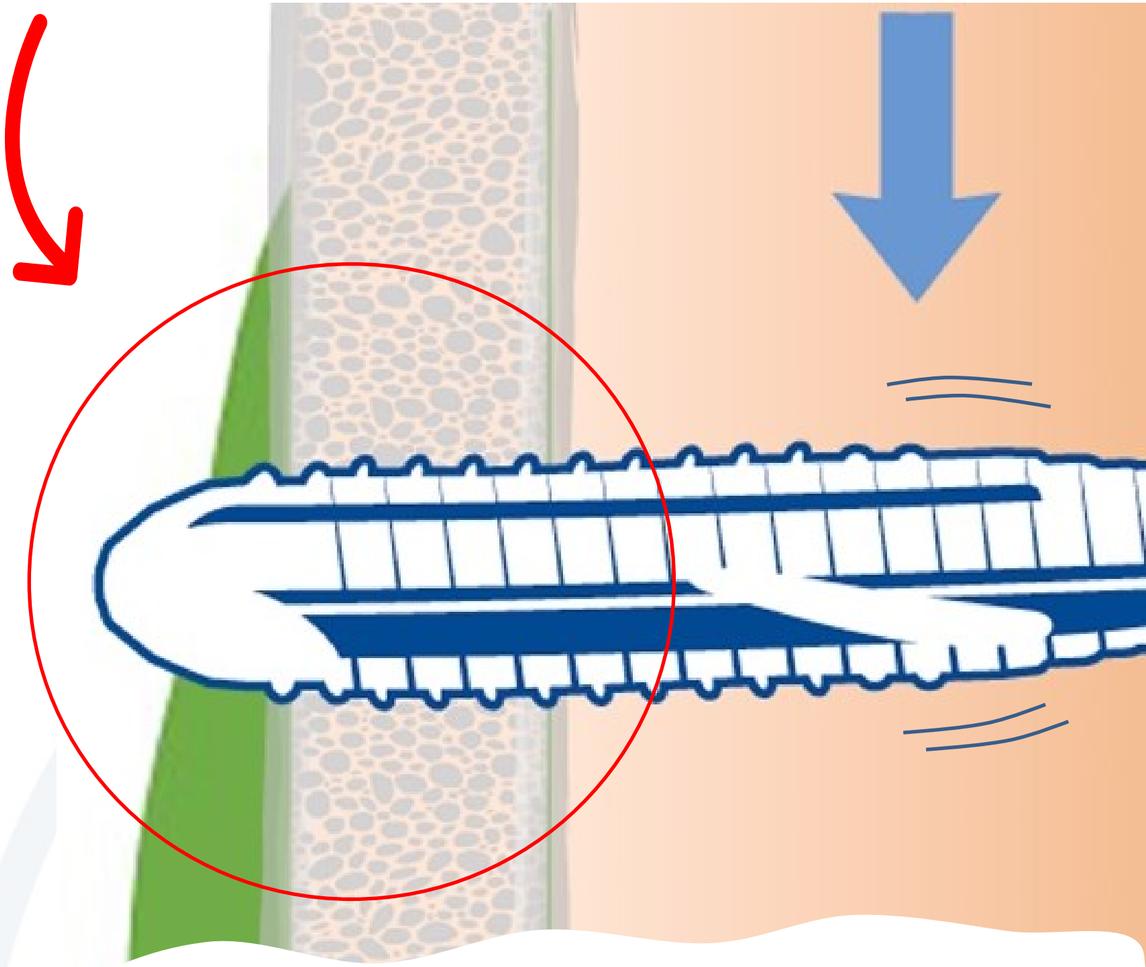
Up to +93% larger bone callus, equally distributed between cortices [12].

Up to +163% bone callus at the cis-cortex [12].

BIOMECH INNOVATIONS

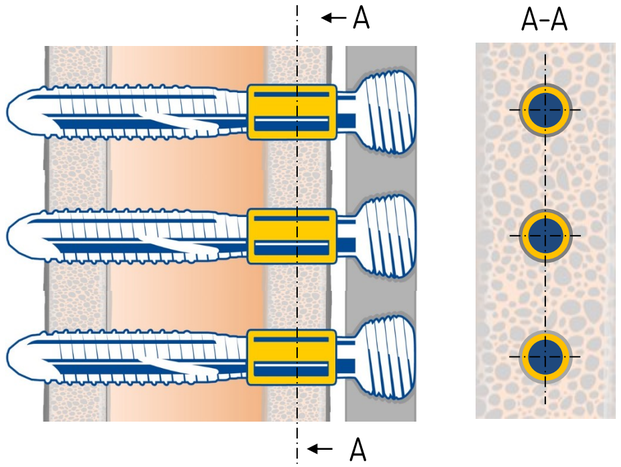
The **periosteum** contains **skeletal stem cells** with the highest bone regenerative potential and reacting to **mechanical stimulation** [13].

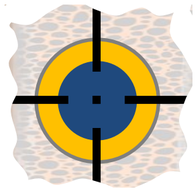
Gradually stimulating the trans cortical periosteum **Variable Fixation Locking Screws** triggers the production of **additional** bone **callus** [12].



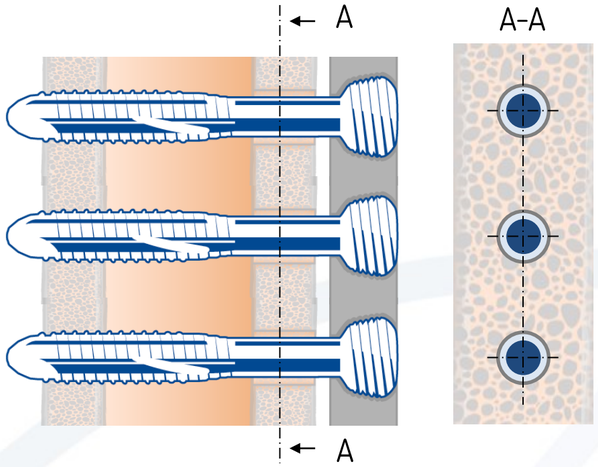
BIOMECH INNOVATIONS

Dynamization and its benefits can be achieved **only when** the surgeon is able to hand-build a construct featuring **all screws truly working in parallel**.

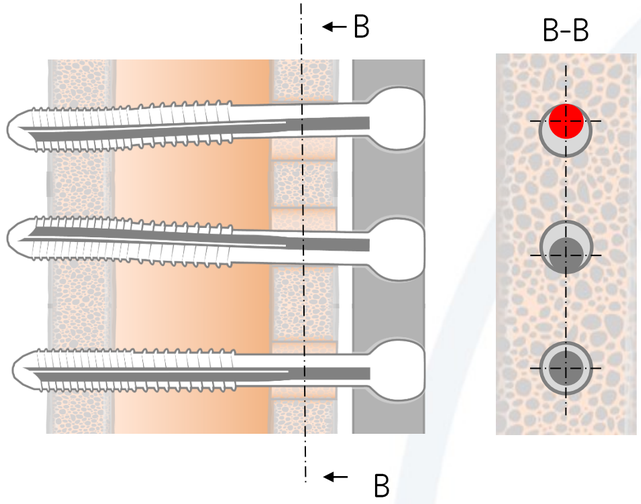




The **sleeve guarantees that** each screw remains at the center of the cis-hole during the insertion of other screws and the **dynamization can safely and effectively take place**.



Without a centering sleeve, screws don't work in parallel. The construct dynamization is extremely **uncertain** [14], one likely consequence is **screw(s) overload** and, potentially, **failure** [15].



Unintentionally positioning the screws, in e.g., in this configuration, the dynamization doesn't take place and one screw carries all the load applied proximally to this segment.

BIOMECH INNOVATIONS

Same surgical technique – follows standard operative workflow.

Complementary solution – replaces existing screws and can be used alongside them.

Hand-built construct friendly – delivers consistent performance when assembled in the surgical theatre.

Construct tuning – allows fine tuning to accommodate for fracture anatomical locations, gap size, patient mass and healing expectations.

Always Stable Fixation – secure locking technology.

Progressive flexibility – gradual increase in construct flexibility.

Progressive dynamization – fosters the formation of bone callus.

Circumferential callus formation – stimulate callus formation under the plate.

One design – titanium and stainless steel, according your preferences.

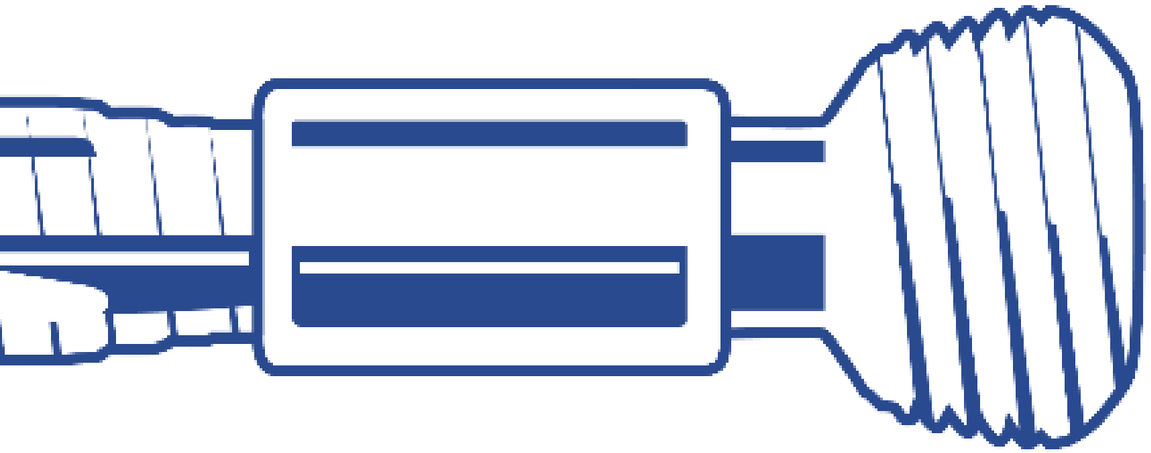
BIOMECH INNOVATIONS

Variable Fixation in peer reviewed scientific journals.

- Variable Fixation Technology Provides Rigid as Well as Progressive Dynamic Fixation: A Biomechanical Investigation.
  J Bone Joint Surg Am. 2020 Jun 26

- Variable fixation promotes callus formation: an experimental study on transverse tibial osteotomies stabilized with locking plates.
  BMC Musculoskelet Disord 21, 806 (2020)

- Strategies to Improve Bone Healing: Innovative Surgical Implants Meet Nano-/Micro-Topography of Bone Scaffolds.
  Biomedicines. 2021 Jun 28;9(7):746



BIOMECH INNOVATIONS

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[12] Variable fixation promotes callus formation: an experimental study on transverse tibial osteotomies stabilized with locking plates. BMC Musculoskelet Disord 21, 806 (2020)

[13] Duchamp de Lageneste, O.; Julien, A.; Abou-Khalil, R.; Frangi, G.; Carvalho, C.; Cagnard, N.; Cordier, C.; Conway, S.J.; Colnot, C. Periosteum contains skeletal stem cells with high bone regenerative potential controlled by Periostin. Nat. Commun. 2018, 9, 773.

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[15] FDA recall “Z-0390-2014”

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How to get more information about Variable Fixation ?

Book today a 1:1 technical briefing
@ www.biomech-innovations.com

FAQ FMS 501-301_vA

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