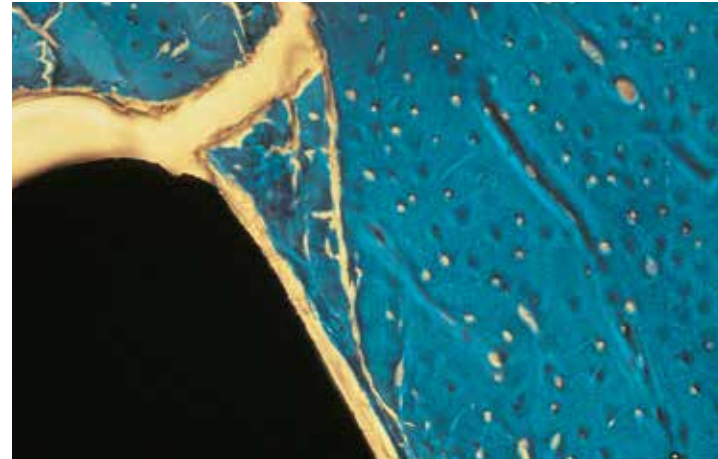
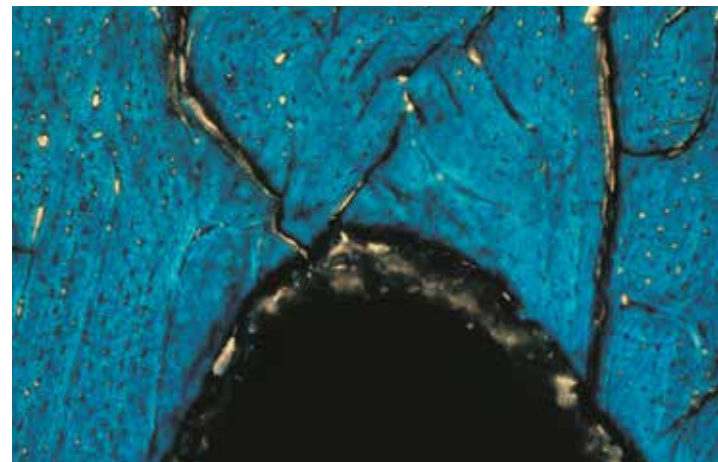


2. Osseointegration

An experimental study¹ comparing uncoated, hydroxyapatite-coated and titanium-coated Orthofix screws was conducted. Osseointegration with direct contact between the bone and the screw thread was seen only with the hydroxyapatite-coated Orthofix screws.



Stainless steel surface: metal screwed into the bone, but no actual bond between them. In a proportion of cases this physical fit breaks down sufficiently to cause macroscopic loosening.



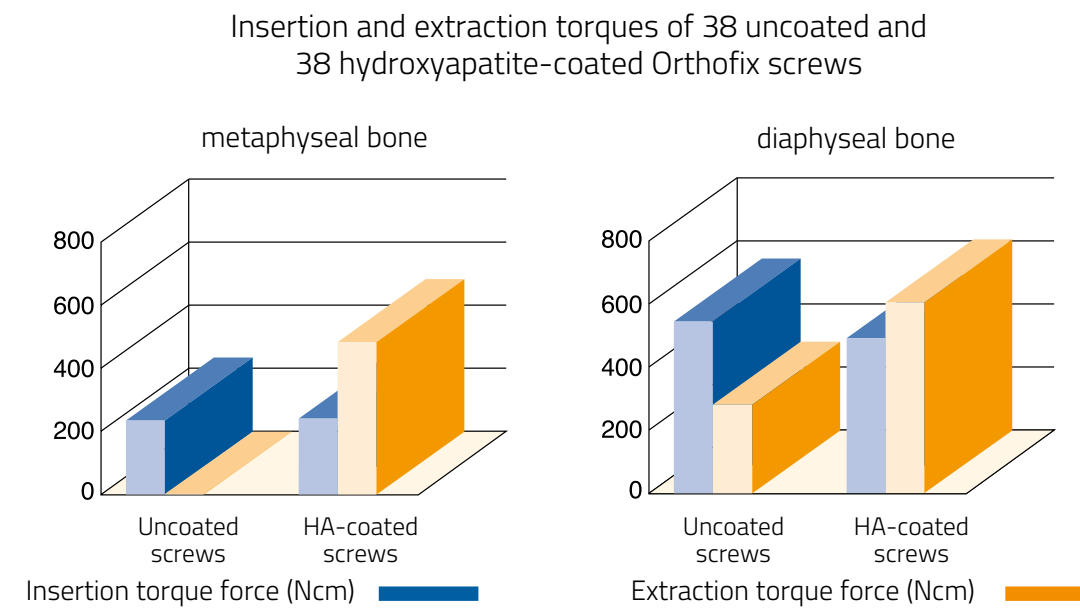
Hydroxyapatite surface: bone grows into and onto the hydroxyapatite so that the border between the two materials becomes indistinct.

This biological bond is a strong anchor which will ensure long-term stability of the bone-screw construct, allowing it to withstand repetitive loading cycles without loosening of the screw.

External fixation is a race between the growing stability provided by callus maturation and the destabilising effect of screw loosening. Preservation of the bone screw interface is the key to a successful outcome.

2. Enhanced Fixation and Reduced Pin Loosening

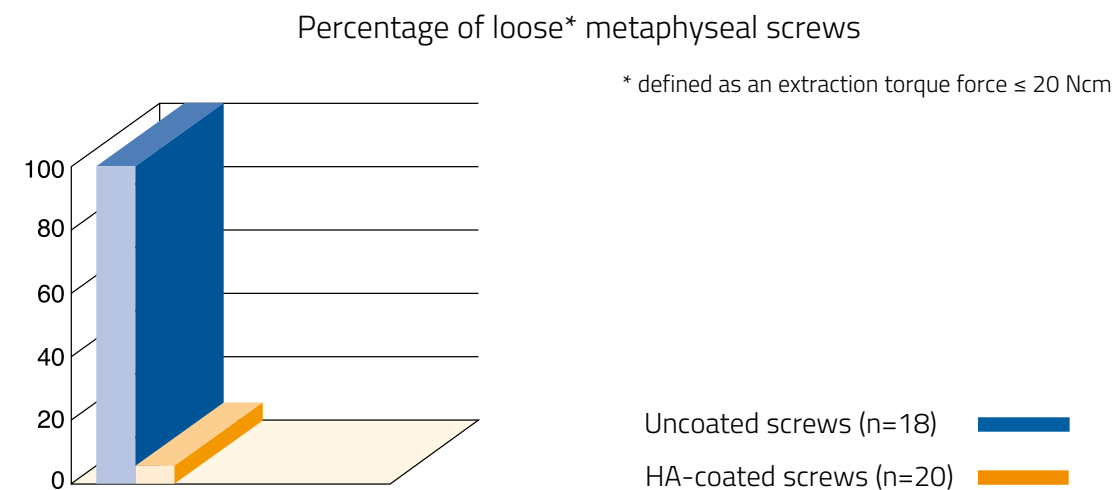
A clinical study² compared insertion and extraction torques of uncoated and hydroxyapatite-coated Orthofix screws.



Mean treatment time: 101 days

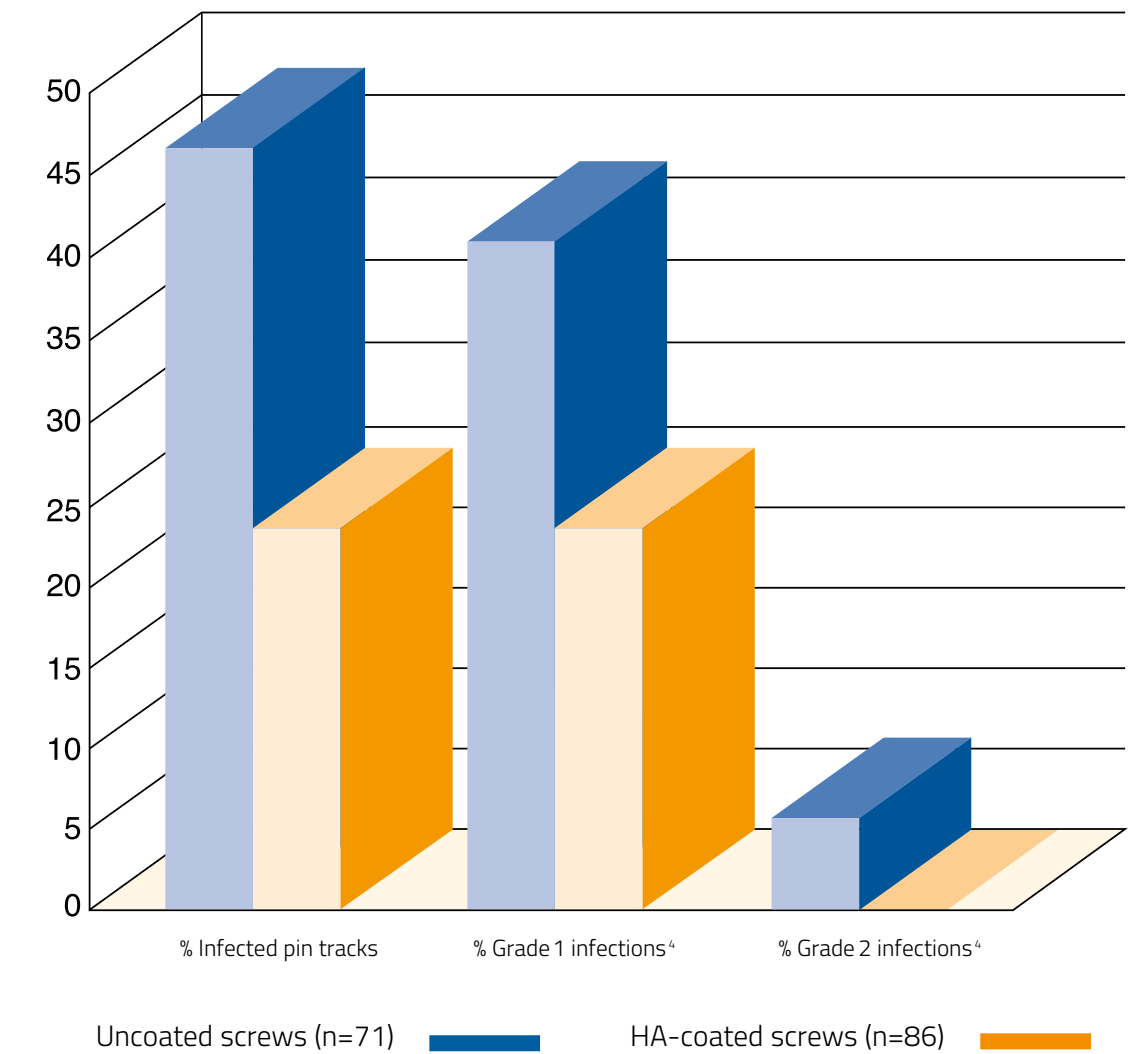
- No significant difference in insertion torque between hydroxyapatite-coated and uncoated screws at either site ($p=0.282$ metaphyseal site; $p=0.268$ diaphyseal site).
- The extraction torque was significantly greater at each site with hydroxyapatite-coated screws than with uncoated screws ($p<0.0001$ in both anatomical sites).
- The extraction torque of the hydroxyapatite-coated screws was significantly higher than the insertion torque at each site ($p<0.0001$ metaphyseal site; $p=0.020$ diaphyseal site), whereas that of the uncoated screws was significantly lower in both anatomical sites ($p<0.0001$).
- It was possible to remove the hydroxyapatite-coated screws without the need for hospitalization, sedation or anesthesia.

The same clinical study² demonstrated a significant reduction in the amount of loosening when hydroxyapatite-coated Orthofix screws were used in metaphyseal bone.



Mean treatment time: 101 days

3. Reduced Incidence of Pin Track Infection



Mean treatment times: Uncoated screws 166 days; HA-coated screws 178 days

- A further clinical study³ demonstrated a significantly lower incidence of pin track infection with hydroxyapatite-coated screws than with uncoated screws ($p<0.05$).
- A significant correlation between pin track infection and implantation in a metaphyseal site was found with the uncoated screws ($p<0.001$), but not with the hydroxyapatite-coated screws ($p>0.12$).

OsteoTite Bone Screws

- Orthofix OsteoTite Bone Screws with Hydroxyapatite Coating may eliminate the need to replace the external fixation system with an alternative treatment for long term therapy.
- Conical thread design:

The hydroxyapatite coating is complemented by the well-established conical design of the Orthofix screws. Each thread cuts a new, slightly larger path in the bone on insertion, providing excellent bone purchase

Available sizes of OsteoTite Bone Screws*:							
Cortical Bone Screws (shaft Ø 6 mm, thread Ø 6-5 mm)							
Total length (mm)	Thread length (mm)						
	30	40	50	60	70	80	90
90	99-60160						
100	99-60162	99-60163					
110	99-60110	99-60100	99-60101				
120		99-60164					
130	99-60139	99-60114	99-60141				
150	99-60142	99-60165	99-60102	99-60111			
160			99-60143		99-60166		
170		99-60144		99-60145		99-60167	
180			99-60103	99-60112			
200			99-60115	99-60116			99-60168
220	99-60612	99-60613					
250			99-60614	99-60615			
Cortical Bone Screws (shaft Ø 4 mm, thread Ø 3-3.3 mm)							
Total length (mm)	Thread length (mm)						
	20	35					
70	99-65100						
80		99-65101					
Self-drilling Cortical Bone Screws (shaft Ø 6 mm, thread Ø 6-5 mm)							
Total length (mm)	Thread length (mm)						
	30	40	50	60	70	80	90
150				99-60146			
160					99-60147		
170						99-60148	
180							99-60149
220	99-60171	99-60172	99-60173				
250	99-60174						
XCaliber OsteoTite Bone Screws (shaft Ø 6 mm, thread Ø 6-5.6 mm)** >Packaged Sterile<							
Total length (mm)	Thread length (mm)						
	30	40	50	60	70	80	90
150	99-611530	99-611540	99-611550	99-611560	99-611570	99-611580	99-611590
260	99-612630	99-612640	99-612650	99-612660	99-612670	99-612680	99-612690

* OsteoTite Bone Screws are supplied sterile.

** XCaliber OsteoTite Bone Screws can be applied also as self-drilling screws.

References

1. Moroni A., Toksvig-Larsen S., Maltarello M.C., Orienti L., Stea S., Giannini S. A Comparison of Hydroxyapatite-Coated, Titanium-Coated and Uncoated Tapered External Fixation Pins. J Bone Joint Surg [Am], 1998; 80-A (4): 547-554. 2. Magyar G., Toksvig-Larsen S., Moroni A. Hydroxyapatite coating of threaded pins enhances fixation. J Bone Joint Surg [Br], 1997; 79-B (3): 487-489. 3. Moroni A., Heikkila J., Toksvig-Larsen S., Stea S., Giannini S. Hydroxyapatite Coated Tapered Pins Are Better Fixed: A Multi-center Prospective Randomized Clinical Study. Presented AAOS 1998. 4. Checketts R.G., Otterburn M. Pin track infection: definition, incidence and prevention. Supplement to International Journal of Orthopaedic Trauma, 1993; 3 (3): 16-18.

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Moroni A., et al. "Improvement of the Bone-Pin Interface Strength in Osteoporotic Bone With Use of Hydroxyapatite-Coated Tapered External-Fixation Pins". JBJS; Vol. 83-A No. 5 (2001).

Green S.A. Complications of external skeletal fixation. Clin Orthop 1983; 180: 109-116.

Mahan J., Seligson D., Henry S.L., Hynes P., Dobbins J. Factors in pin tract infections. Orthopaedics, 1991; 14: 305-308.

The Orthofix Quality System has been certified to be in compliance with the requirements of:

- Medical Devices Directive 93/42/EEC, Annex II-(Full Quality System)
- International Standards ISO 13485 / ISO 9001 for external fixator devices, implants for osteosynthesis and related instruments.



See Manual 1 "Orthofix External Fixation: Basic Considerations" for correct technique of screw insertion

SINGLE USE ONLY

STERILE R

Complications of external fixation include pin track infection and loosening

It is generally accepted that a loose pin leads to an increased risk of infection

The enhanced fixation and improved stability at the pin-bone interface seen with Orthofix OsteoTite Bone Screws with Hydroxyapatite Coating significantly reduces the incidence of pin loosening and therefore reduces the risk of infection

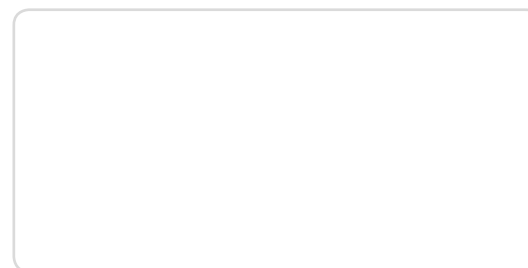
TECHNICAL MONOGRAPH



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Instructions for Use: See actual package insert for Instructions for Use.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

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