XCaliber Screws

ORTHOFIX®
Orthopedics International

Orthofix approach to Evidence Based Medicine:

For years, clinical decision-making was based primarily on physician knowledge and expert opinion. Now the medical community is searching for measurable outcomes "validating" efficacy of treatments. EBM is an approach that integrates individual clinical expertise with the best available evidence when making decisions about patient treatment. (Nierengarten M.B. et al. Using Evidence Based Medicine in Orthopaedic Clinical Practice: The Why, When, and How-To Approach. Medscape Orthopaedics & Sports Medicine. 2001;5(1)).
There has been a significant growth in evidence based medicine over the last few years.

Document Objective:

This document provides a brief summary of the technical and scientific information of the design features of the XCaliber screws, how they benefit to the potential users.
It also includes a glossary of terms and a bibliography of articles to consult for more information on the technical and scientific reasons for choice of these product features.

To receive a digital copy of this "Voice of design" please submit your request to:

Clinical Affairs Dept:
Email: clinicalaffairs@orthofix.com
Phone: +39 045 6719000

INDEX

1.0 DEFINITIONS

Conical shape: characteristic description of a nail whose diameter progressively changes from the proximal end to the distal end.

Thread profile: this describes the complete shape of a screw thread and includes the values of each geometric property.

Pitch: distance between two crests of a thread.

Fine pitch: if the distance between two crests is less than 1.5 mm, it is considered to be a “fine pitch”.

Osteolysis: localized loss of bone tissue, so that only its connective structure remains, due to a number of different causes. In radiographic examinations it appears as a well-defined region which is less dense than the surrounding bone tissue.

Stripping: removal of the threads made in the bone by the self tapping or self drilling screw.

PPI (pin performance index): ratio of insertion to extraction torque.

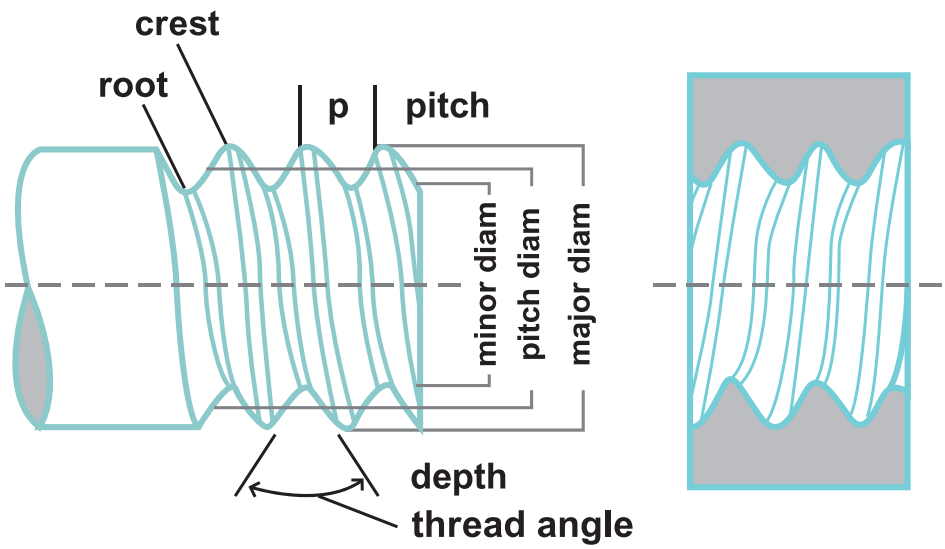

Fig.1 Detail of the thread screw

2.0 SCREW DESIGN

2.1 Fine Thread Pitch

In the XCaliber screws, the distance from the crest of one thread to the crest of the next is 1.25 mm.

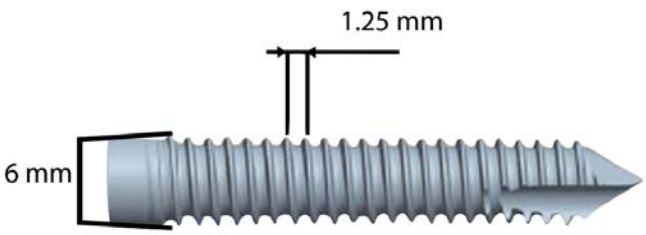

Fig.2 Details of dimensions of the XCaliber screw.

The choice of fine pitch for the thread attenuates the stripping effect during insertion and damage to the bone, reducing loss of bone mass. These two benefits promote greater bone integration around the screw.

[Gausepohl T, Mohring R, Penning D, Koebke J. Fine thread versus coarse thread. A comparison of the maximum holding power. Injury 32 (2001) S-D-1-S-D-7]

The only disadvantage of fine thread is that more turns are necessary to insert the screw, as each turn corresponds to a shorter distance moved.

2.2 Low Thread Profile

Choice of low thread profile (Fig. 3) translates into a 17% increase in the screw/bone contact surface thanks to the fine pitch of the thread.

Fig.3 Screw thread profile.

When screw loading occurs, this profile produces a reduction in point pressure and the optimization of stress distribution, that reduces the phenomenon of osteolysis. Finite Element Analysis conducted by Orthofix assessed the area of contact at the screw/bone minterface in relation to different thread profiles. Compared to other designs, the XCaliber profile, which is also used for the Veronail cephalic screws, is superior.

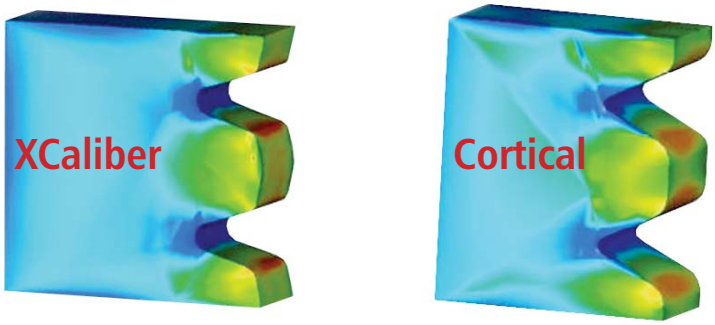

Fig.4 Finite element analysis at the bone/screw interface on different types of screws

Thread	mm^2
Cortical Screw	18.01
XCaliber Screw	21.06

Tab.1 bone/screw contact surfaces

[Internal report]

2.3 Combined effect

The low profile and fine pitch of the thread reduce the stripping effect both during insertion of the screw and under loads. These two effects attenuate the formation of micro-cracks (microscopic lesions) during insertion.

Analyses conducted by the Royal Vet College, UK (Prof. Goodship), at the Anatomy School of the University of Cologne (Prof Koebke) in vivo and ex-vivo and at St. Vincenz Hospital, Cologne (Prof D. Pennig) have confirmed this effect.

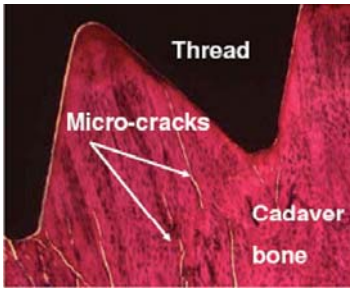

Fig.5 Histological image at the bone/screw interface

2.4 Geometric Shape of the Tip

The tip of the screw plays a very important role in relation to the screw's functioning, implantation and holding power.

The design of the tip is optimized for easy entry into the first cortex with reduced time penetrating the bone, ensuring stable contact between the screw and the bone surface. This is due to the small front tip of the screw, the cutting angles and efficient cutting and removal of the bone chips, to the outside of the bone for the first cortex into the marrow canal for the second cortex.

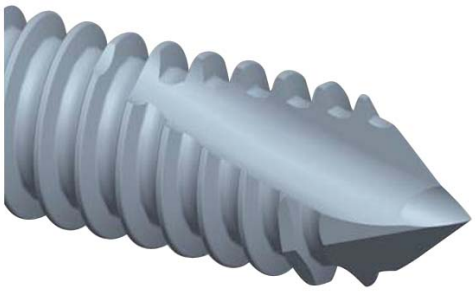

Fig.6 Detail of tip of XCaliber screw.

The speed of forward motion per revolution (linked with pitch) is lower than for ordinary selfdrilling screws, and this, along with the geometric shape of the front surface, creates a proper thrust - cut approach to the second cortex. In strong cortex walls - especially those of a thickness comparable to the length of the "flutes" - there may be limited release of chips. This may translate into excessive resistance to forward motion or in slight deviation with respect to the perforation path. It is therefore important to take the usual precautions applied in general surgical technique: if the screw starts to feel very tight, unscrew it, remove any impacted bone material, wash the screw thread in saline and reinsert it.

NB. If the screw has been subjected to excess load during attempted insertion, it is worth considering using a new one to reduce the risk of breakage.

2.5 Conical Shape

The diameter of the thread increases from the screw tip to the junction with the shank (from 5.6 mm to 6 mm). This conical shape produces radial pre-load: as the screw is inserted, the smaller distal end makes the initial path through the bone. As the screw advances, its diameter increases exerting radial pressure on the first cortex. This results in less osteolysis and improves the holding power of the screw.

This compression caused by the radial pre-load ensures that bone adheres perfectly to the screw profile, promoting bone integration.

An animal study conducted by Orthofix at the Royal Vet. College (UK) compared the holding power (PPI: pin performance index) of the fine threaded conical screw to a standard cortical screw. The results revealed that the combination of these two design features (conical shape and fine thread) leads to a better PPI value with less pin loosening.

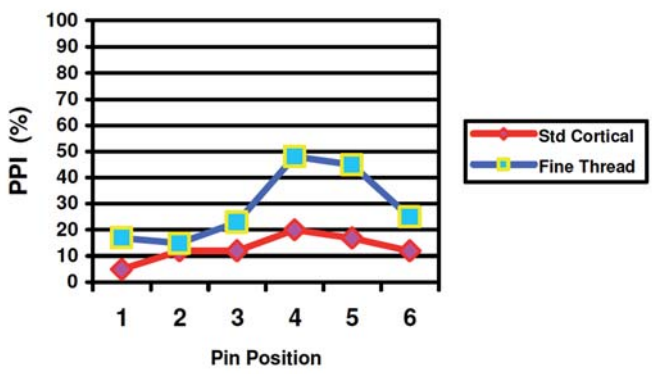

Fig.7 PPI variation in different screw positions

[Internal Report]

Manufactured by: ORTHOFIX Srl
Via Delle Nazioni 9
37012 Bussolengo (Verona)
Italy

Telephone +39-0456719000
Fax +39-0456719380

CE 0123

Distributor:

www.orthofix.com
XC-1101-VOD-E0 A 01/11

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Orthopedics International