

A mechanical and clinical evaluation of the "Helix Wire" for subcapital humerus fracture osteosynthesis

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The aim of this paper is the investigation of the mechanical properties the Helix Wire, a device that has been employed for subcapital humerus fracture osteosynthesis in recent years. There are several potential clinical advantages associated with its use, but clinical results reported in literature are controversial.

The Helix Wire has been assimilated to a helical spring, and several analytical solutions for displacements and stresses have been compared and experimentally validated, showing the importance of the pitch angle contribution.

Based on the results, the main factor for the clinical indication of this fixation device was found to be the patient age. In fact, the use of the Helix Wire should be avoided in case of young patients or of patients with well-developed muscular masses, where the forces may easily lead to critical stresses in the spring and separation of the fracture surfaces. The clinical results obtained on 30 elderly patients confirmed these findings.

Key words: springs, Helix Wire, minimal osteosynthesis, humerus neck fracture

1. Introduction.

Helical implants and helical intramedullary implants for bone fixation are gaining an increasing interest for clinical uses. In fact, the geometrical properties of the helix lead to interesting considerations when the design of implants is addressed.

While the spiral is a flat curve, the helix is a three-dimensional curve lying on a cylinder or cone, so that its angle to a plane perpendicular to the axis is constant [1]. It is characterized by its axis, radius

and pitch. Special types of helix include the straight line (radius = 0 or pitch = infinity) and the circle (pitch = 0).

The 3D solids obtained by extrusion over a helical path have a property that is particularly interesting with regard to the design of implants: the “sword-sheath” situation. Thinking of the implant as of a sword that must be inserted in a tight fitting sheath - the bone - it can be easily recognized that there are three shapes of sword that are suitable for this purpose: the straight, the circle and the helical sword. As already mentioned, the first two geometries can be regarded as special types of the third.

The property holds also the other way round: if a 3D solid meets the criteria for the “sword-sheath” situation, then it is an extrusion over a helical path. Based on the previous considerations, and with the goal of minimizing the tissue damage while facilitating the insertion and removal of the implant, novel possibilities for fixators and nails based on a helical geometry have been examined in [2].

The Helix Wire [3], a device that has been employed for subcapital humerus fracture osteosynthesis in recent years, is also based on a helical geometry. The aim of this paper is the investigation of its mechanical properties and consequent clinical indications.

The Helix Wire is produced by Implantat Technologie Systeme GmbH (Graz, Austria) and consists of a titanium helical spring with a round cross section, as shown in Fig.1.

The device is inserted into the intramedullary canal through a small lateral incision (Fig.2). It is then rotated up into the head fragment until it bridges the fracture. The fixation of the fracture is obtained in three points: the lateral cortical, the median cortical and the trabecular part of the humerus head (Fig.3). The fixation achieved with the Helix Wire is semi-rigid and is able to generate the micro-displacements at the fracture surface that are known to facilitate the healing (Fig.4).

Developed at first for functional fractures in osteoporotic bone, the Helix Wire is applied for subcapital humerus fractures (displaced or not) that do not irradiate to the head, since in this case the third fixation point would miss.

There are several potential clinical advantages associated with the use of the Helix Wire:

- ❑ Minimally invasive surgery procedure;
- ❑ Minimal stress for the patient;
- ❑ Immediate pain remission;
- ❑ Quick fracture healing;
- ❑ Removal of the implant is not necessary;
- ❑ No migration, always possible with Kirschner threads.

Nevertheless, clinical results reported in literature are controversial [4-10].

Consequently, a study has been carried on in order to obtain precise indications for the use of this osteosynthesis device and avoid undesired outcomes.

2. Materials and methods.

The Helix Wire is manufactured in Ti-6Al-4V ELI Titanium alloy. The unique properties of this alloy combine biocompatibility with attractive mechanical properties, inherent workability and commercial availability that lead to reliable and economic usage. Moreover, its high strength efficiency (strength to density ratio) has been suggested to play a role in patient perception of the efficacy of the implant [11]. The physical and mechanical properties of Ti-6Al-4V ELI are shown in Table 1 [12].

From the mechanical point of view, the Helix Wire can be regarded as a tension helical spring of round cross section, characterized by a particularly large pitch angle. Dimensions of the sample available for the study are shown in Table 2.

Displacements. There are several formulas available for the displacements.

(a) Books on strength of materials often neglect the pitch angle and evaluate the displacement of the spring end simply considering the spring as a round straight bar subject to torsion [13, 14]. When load P is applied, the spring elongation f of an n coil spring with this hypothesis is given by

$$f = n \frac{4PR^3}{Gr^4}. \quad (1)$$

(b) A common design formula by Wahl [15], based on an elementary consideration of pitch, gives the spring deflection $f_{(w)}$ by applying a correction coefficient $\psi_{(w)}$ to the expression (1):

$$f_{(w)} = n \frac{4PR^3}{Gr^4} \psi_{(w)}, \quad \psi_{(w)} = 1 - \frac{3}{16} \left(\frac{r}{R} \right)^2 + \frac{1-\nu}{2(1+\nu)} (\tan \gamma)^2 + \dots \quad (2)$$

where $\tan \gamma = \frac{p}{2\pi R}$.

(c) Ancker and Goodier in [16] derived a more accurate expression for spring deflection by a thin-slice method: the unloaded spring may be considered as a number of identical thin slices all glued together. The method is applicable when the cross section and applied loads are the same throughout the body. After loading, the final position of a typical cross section will be specified by a rigid motion of the slice (that is different for the different cross sections) plus a warping and distortion of the slice (that is the same for all of them). Displacements were deduced from considerations of symmetry and expressed as a doubly infinite power series in the parameters (r/R) and γ (pitch angle, $\tan \gamma = p/2\pi R$), substituted into the equations of the boundary-value problem. Details of the solution may be found in [17]. The resulting expression for spring deflection $f_{(w)}$ is

$$f_{(A)} = n \frac{4PR^3}{Gr^4} \psi_{(A)}, \quad \psi_{(A)} = 1 - \frac{3}{16} \left(\frac{r}{R} \right)^2 + \frac{3+\nu}{2(1+\nu)} (\tan \gamma)^2 + \dots \quad (3)$$

where again formula (1) is modified by a correction coefficient $\psi_{(A)}$.

Stresses. The greatest stresses are at the inner point on a horizontal diameter of the cross section.

The usual notation for a cylindrical system of coordinates is used.

(a) The simplest formula assumes only the torsional shear on a round straight bar plus an uniform distribution of direct shear:

$$\tau_{\theta z} = \frac{2PR}{\pi r^3} \left[1 + \frac{1}{2} \left(\frac{r}{R} \right) \right]. \quad (4)$$

(b) Wahl [15] considered the torsional shear on a curved bar plus the bending shear on the neutral axis of a round cantilever beam as in the theory of elasticity:

$$\tau_{\theta z(w)} = \frac{2PR}{\pi r^3} \left(\frac{4c-1}{4c-4} + \frac{0.615}{c} \right). \quad (5)$$

where $c = R/r$.

(c) The complete solution, obtained by Ancker and Goodier [16] from the above displacements, is

$$\begin{aligned} \tau_{r\theta} = \tau_{rz} = \sigma_r &= 0 \\ \tau_{\theta z(A)} &= \frac{2PR}{\pi r^3} \left[1 + \frac{5}{4} \left(\frac{r}{R} \right) + \frac{7}{8} \left(\frac{r}{R} \right)^2 \right] \\ \sigma_{\theta(A)} &= \frac{2PR}{\pi r^3} \left[\frac{-2 + \nu + 4\nu^2}{4(1+\nu)} \left(\frac{r}{R} \right) \tan \gamma \right] \\ \sigma_{z(A)} &= \frac{2PR}{\pi r^3} \left[2 \tan \gamma + \frac{11 + 12\nu}{4(1+\nu)} \left(\frac{r}{R} \right) \tan \gamma \right]. \end{aligned} \quad (6)$$

Experimental test. In order to assess the accuracy of the solutions available in literature, the characteristic curve of the Helix Wire has been experimentally determined. The applied load was increased in successive steps, and the elongation of the spring was measured with a capacitive sensor. The loading system had the effect of reducing the number of active coils to 11.5.

The Helix Wire exhibited a linear characteristic up to a 130 N load. The experimental elastic constant for the spring with 11.5 active coils was 11.35 N/mm.

3. Results.

The results obtained by the experimental test on the 11.5 coils spring were used to validate the analytical models. From these data, it was successively possible to compute the elastic properties of the single coil and of the complete 13 coils Helix Wire.

In Fig.5 the experimental curve is compared with the analytical results. It can be seen that while the correction introduced by the Wahl coefficient is not sufficient, the expression by Ancker and Goodier shows a very good agreement with the experimental data. This model has been therefore employed to evaluate the elastic constant of the complete 13 coils Helix Wire, $K = 10$ N/mm.

The characteristic curve of the single coil is shown in Fig.6. In order to quantify the micro-displacements at the fracture surface, the application of a 50 N load, that is approximately the

weight of an average human arm, leads to a single-coil elongation of 380 μm . Dynamic micro-displacements of this magnitude are known to help the healing process.

The non-null stresses computed with the Ancker and Goodier model are shown in Table 3. The von Mises stress has been then computed and compared with the yield strength of the alloy, leading to the definition of a critical value of load for the examined Helix wire: $P_{cr} = 130 \text{ N}$.

When the arm is moved, the inertial loads more than double its weight, and the total load acting on the implant can therefore easily approach the critical value.

Especially in case of young patients or of patients with well-developed muscular masses, the forces involved may easily lead to critical stresses in the spring and to separation of the fracture surfaces due to the permanent elongation of the spring. Consequently, patient age appeared to be the main factor for the clinical indication of this fixation device.

4. Clinical test.

Between January and September 2003, a total of 30 patients (7 males and 23 females ranging in age from 74 to 93 years) with fracture of the humeral neck received a Helix Wire implant. The fracture involved the right side in 18 cases and the left in 12. Of the 30 patients, 9 had nondisplaced or minimally displaced fractures and the other 13 showed fracture lines radiating to the humeral head but without fragmentation of the head. The time interval between injury and surgery never exceeded three days.

The surgical procedure was carried out with the patient in a half-seated position (beach-chair position) and the use of an image intensifier. The fractures were reduced and synthesised with the Helix Wire. The implant was positioned 2-3 mm below the cortical bone of the humeral head. The distal end of the Helix Wire was then shortened so as to leave a 10-15 mm segment in extracortical position. After post-operative radiography, the planes were sutured and a sling applied for 30 days.

The patients, albeit wearing the sling, immediately started physiotherapy that included both active and passive movements. Serial radiographic follow-up examinations were performed at 30 and 60 days.

The clinical and functional assessment of the patients treated with the Helix Wire was performed using the Constant and Murley score [18], a 100-point scoring system based on a 35% of subjective parameters (pain, daily activities) and a 65% of objective parameters (range of active motion and strength). This system is a standard for all conditions and surgical procedures, as functional assessment with this system is evaluated independently of diagnosis and treatment.

Patients reporting no pain after physiotherapy were assigned a score of 15, if they had mild pain they were assigned 10, moderate pain 5 and severe pain 0. Furthermore, if the patients were able to perform all the activities of daily living they received a score of 20, if not, the score was reduced according to the activities they were able to carry out. Range of motion was assigned a score of 40, 10 for elevation of the arm, 10 for abduction, 10 for intrarotation and 10 for extrarotation. Strength was given a score of 25 if the patient was able to maintain a 90° abduction.

The clinical and functional assessment yielded the following results: excellent in 44 cases, good in 17 cases (score ranging from 75% to 98%), fair and sufficient in 8 cases and poor in 1 case due to implant migration. Compared to the results obtained with other non-invasive or surgical techniques, these findings appear to demonstrate the value of the technique used. In all of the cases considered excellent, good, fair and sufficient the fractures healed; there was no infection, pseudoarthrosis or vascular osteonecrosis.

5. Conclusions.

The mechanical properties of the Helix Wire, a device employed for subcapital humerus fracture osteosynthesis, have been investigated in order to obtain precise clinical indications for its implant. The Helix Wire has been assimilated to a helical spring, and several analytical solutions for displacements and stresses have been compared and experimentally validated, showing that the use of Helix Wire should be avoided in case of young patients or of patients with well-developed muscular masses, where the forces may easily lead to critical stresses in the spring and consequent separation of the fracture surfaces.

On the basis of the clinical results obtained in 30 elderly patients, the Helix Wire proved to be highly effective provided that the following main indications are strictly observed: humeral neck nondisplaced fractures and displaced fractures without involvement of the humeral head (third fixation site); elderly patients in whom the extent of the forces bearing on the fracture points are unlikely to interfere with the implant mechanical characteristics.

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Table 1

Ultimate tensile strength	R_m	1000 MPa
Yield strength, 0.2% offset	R_y	900 MPa
Modulus of Elasticity, tension	E	114000 MPa
Modulus of Elasticity, torsion	G	42200 MPa
Poisson's ratio	ν	0.33

Table 2

Cross section radius	r	1 mm
Mean coil radius	R	4 mm
Spring pitch	p	12 mm
Spring length	L	150 mm
Number of coils in spring	n	13

Table 3

$\tau_{\theta z}$	σ_{θ}	σ_z
$3.48 P$	$-0.07 P$	$3.31 P$

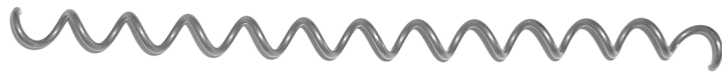


Fig.1: The Helix Wire



Fig.2: The small insertion incision

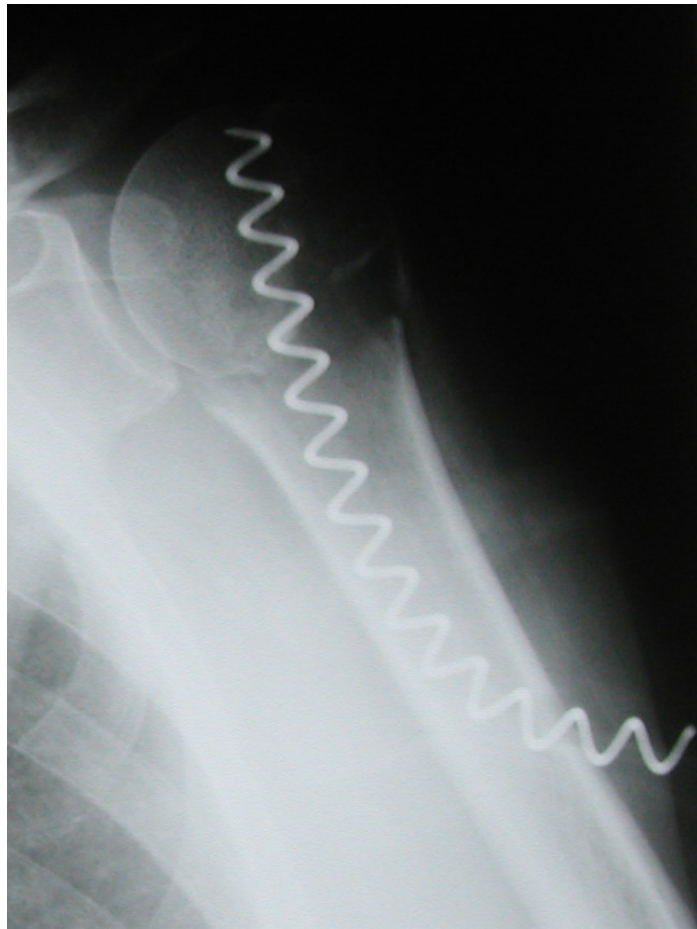


Fig.3: The three-point fixation.



Fig.4: The healed fracture

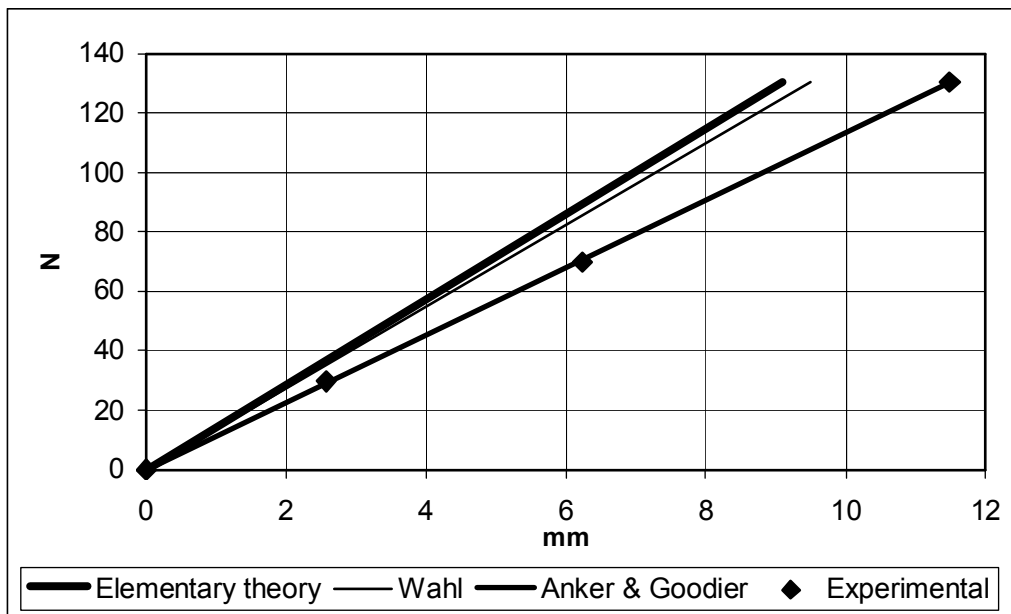


Fig.5: Experimental and analytical results

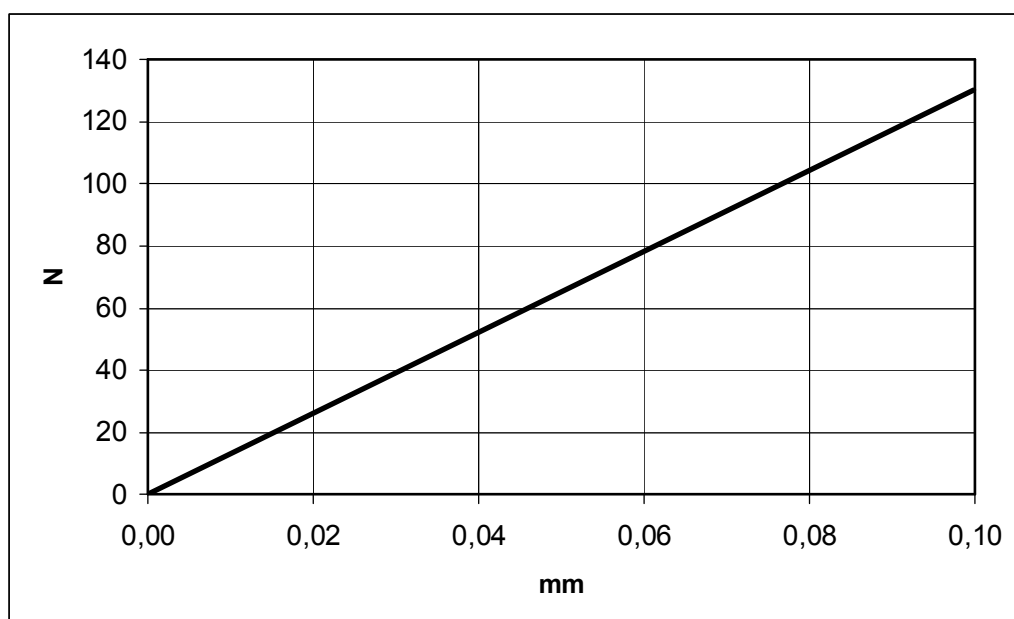


Fig.6: Characteristic curve of the single coil