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Material analysis of a broken gamma nail

Abstract

The gamma locking nail is well proven for fracture repair of the thighbone in the region of the trochanter or for combined types with involvement of the metaphysis[1, 2, 4, 6, 7]. Quite often partial weight bearing in the post-operative phase can be allowed. Mainly elderly patients who, due to poor coordination and strength, are rarely able to walk with partial weight bearing on crutches or a rolator, benefit from that fact.

In the phase of mobilisation, breakage of implants is observed in the clinical day-to-day routine[5, 8, 9, 10, 11]. Nearly without exception, material failure occurs in the phase of full weight bearing, but always before consolidation of the fracture, so that a revision operation with a new implant of osteosynthesis material always has to be performed.

Based on those facts, a material analysis of two newly manufactured gamma nails of 200-mm length was performed. This was followed by a chemical analysis, an evaluation of purity, and a test for course of hardness. Hereby an unusually high number of non-metallic inclusions were found. The results were compared with the demanded abilities of surgical steel according to DIN (German Institute for Standardization) 17443. Our results show that the sulfidic inclusions

were above the demanded maximum of the norm, indicating that a poor grade of purity may be responsible for breakage of the surgical implants.

Introduction

Nowadays our population contains a greater proportion of elderly people and is therefore experiencing age-associated illness at a much higher extent than in earlier decades. This means an increase in care taking of fractures at the coxal end of the femur. Preoperative symptoms and a decrease in mobility are often established with the predominantly older patients. Inevitably, the avoidance of immobility, early operation after occurrence of accident, early mobilisation, postoperative ability for straining as well as a gentle, blood saving, and time sparing method of operation are therefore derived as the main principles of fracture repair[3].

The development of new materials in osteosynthesis for joint pertaining operations originated in these requirements. Besides the long established dynamic hip screw, the gamma nail has been used since the eighties. A nail for intramedullary insertion was combined with a hip screw to guarantee axial stability, as well as dynamic compression on the fracture. Rotational movement can be avoided by means of two distal reaming screws.

To complete the picture, there is also the proximal femur nail (PFN) that has been available for some time (Synthes, Switzerland) and has a similar construction as the gamma nail. The most striking difference is a second screw, called a “gliding screw” by the manufacturer, which is smaller in diameter and has to be fixed in the neck of the femur.

Materials and Methods

Since 1988, longer versions (340, 360, 380, 400, 420, 440-mm) have been offered after the establishment of the standard implant length of 200-mm. According to manufacturers information, the long gamma nail may be used with long subtrochanteric fractures, combinations of pertrochanteric and diaphysical fractures, as well as pathological fractures of those areas.

In one case study, a 340-mm long gamma nail was inserted in a lengthy subtrochanteric thigh fracture of a 72-year-old, slim female patient. No specialities occurred throughout the operation and the early hospital mobilisation. The patient was dismissed on partially weighted crutches a fortnight after surgery. After 4 weeks, control x-rays were taken and showed the correct, unchanged situation of the osteosynthetic material and formation of callus material, so the patient was permitted full weight bearing. Further control x-rays performed after eight and twelve weeks proved increasing fracture consolidation.

At six months after fracture repair, the patient was readmitted for ambulant examination with severe weight bearing related pain located in the upper thigh bone. X-rays taken at clinical examination revealed a fracture of the implanted gamma nail. Therefore another 340-mm gamma nail was implanted in a revision operation. Complete fracture consolidation was later established. The implant was removed 19 months after initial treatment.

Several times, implant failure of the standard, as well as of the long version was observed in our patient pool, promting us to further investigate the reasons for failure.

Conditions for Surgical Implants

The materials used for surgical implants are commonly cylindrical rolling and forging products made from stainless steel. The technical delivery conditions for these materials are combined in DIN 17443 and ISO (International Organisation for Standardisation). This should guarantee on delivery to the implant producers that the type of steel used is well tolerable and free of the possibility to corrode. In the case of the combination of two materials, it should furthermore guarantee the avoidance of contact corrosion and the “local element” emergence.

In accordance to DIN 17443, the steel used in gamma nails is steel of No. 1.4461 with the DIN short code X2CrNiMnMoN22136.

Results

The breakage of the nail occurred 130-mm distal from the tip. Upon visual inspection, both the short as well as the long fragments showed a progressed rounding in the sense of pseudo-polishing, probably due to high mechanical wearing. Due to that fact, there was no topographical ness evident for closer breakage evaluation. This suggests that a partial breakage was established over a long interval. Apparently during walking movements, the fragment ends were progressively wore down due to corresponding micro movements on the vertical plain upon loading pressure, until the material broke entirely. Under a stereo microscope, areas of constant break with remaining break were visible as correlate for a violent break. This observation supports the postulated course up to the failure of the implant (Fig. 1, 2).

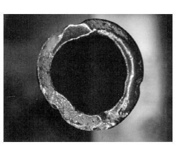

Fig. 1

Fig. 2

Fig 1, 2: Areas of constant break with remaining break as correlate for a violent break on stereo microscopic pictures.

Chemical Analysis

The evaluation of components was performed through the melting analysis of two randomly chosen, newly manufactured gamma nails of 200-mm length. The chemical composition was compared with the types of steel listed under DIN 17443. No deviation from the norm was observed (Table 1).

Element	**Content (%)**	**1.4461 according DIN 17443**
Cu	0,03	No listing
Mn	6,2	5,5 - 7,5
Ni	13,4	10,0 - 16,0
Si	0,38	≤ 0,75
Cr	22,6	21,0 - 23,0
P	0,02	≤ 0,025
S	≤ 0,005	≤ 0,010
Co	n.n	No listing
V	0,06	No listing
Nb	0,34	0,10 - 0,25
Mo	3,15	2,7 – 3,7
C	≤ 0,01	≤ 0,030
Al	≤0,04	No listing
N	n.n.	0,35 - 0,50

Table 1: Components by melting analysis / DIN 17443

Degree of Purity

In DIN 17443, minimal values for the microscopical degrees of purity of the types of steel used are stated. An examination for non-metallic inclusions was carried out in accordance to DIN 50602 (contains regulations for metallographic examination procedures). In the non-cauterised state, excess from the demanded standards of sulfidic inclusions and oxides from aluminium acetate solution were evident. The remaining inclusions were within the expected range.

Inclusions	**Results**	**Values according to DIN 17443**
Sulfidic inclusions	1,2	0,1 - 1,1
Oxides from aluminum acetate solution	3,2	0,1 - 1,1
Oxides from silicate	Below max.	5,3 - 6,2
Oxides of globular form	Below max.	8,2 - 9,3

Table 2: Values of determined non-metallic inclusions.

Within the structural analysis, although not listed in DIN 17443, non-metallic inclusions were examined for frequency of their occurrence in a cauterised state in V2A-stain. The types of steel that show cubic-surface centered crystal form, called austentic steels after discoverer Robert Austen, are particularly suitable for surgical implants. Those steels are heat and corrosion resistant, as well as paramagnetic. In general, those types of steel show only a few non-metallic inclusions. In the case of the two examined nails, there were an exceptionally high number of inclusions despite the normal material characteristics evident.

Fig. 3

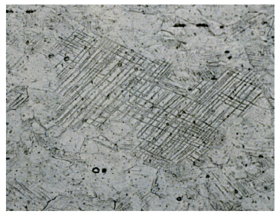

Fig. 4

Fig. 3,4: Lines of deformation in the Austenit corn. Depending on orientation of the corn, the direction of the lines of deformation changes (Corn size approx. 20 µm). Fig. 4: Detailed picture from Fig. 3.

Course of Hardness

The different grades of hardness on the course of the longitudinal axis of a standard length 200-mm gamma nail were measured in accordance to DIN 501050. A tensile strength between 1140 and 1277 N/mm^2 was ascertained after conversion of the measured figures (Fig. 5).

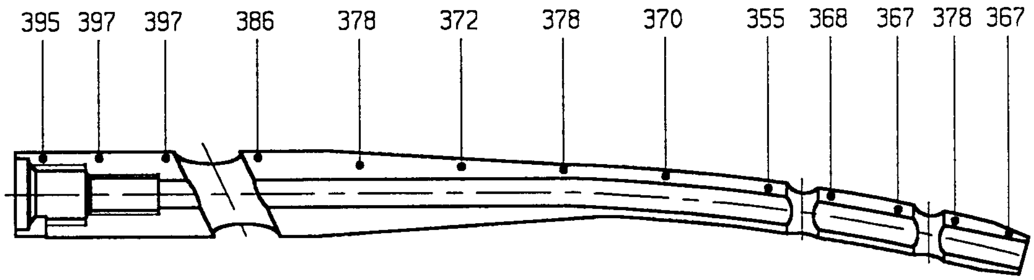

Fig. 5

Fig. 5: Degrees of Hardness.

Summary

Under examination with a magnet, it was proven that the gamma nail belongs to the group of austenetic materials. Reason for complaint gave the values established in the measuring of grade of purity. With sulfidic inclusions and with aluminium oxides, the characteristic values (see Table 2) were higher than in the corresponding DIN 17743 specified. The frequency of other, non-metallic inclusions was exceptionally striking and had to be categorised as unusually high for an austentic material. However, in the standard norm there is no maximum total value listed.

The kinds of delivery conditions that should be fulfilled by the manufacturers are listed in detail in DIN 17443. All conceivable possibilities for the use of later surgical products should be derived from that. Nevertheless, those details leave the manufacturers with the responsibility of choosing the original basic materials. A stricter ad-

herence to the according norm or the introduction of the maximum total value of non-metallic inclusions would guarantee the basic conditions of the materials used by the manufacturers. This would be a sensible proceeding to ensure high quality medical care.

The here presented examination allows the assumption, that, besides other (here not examined) factors, a poor grade of purity can very well be responsible for a reduction in lasting strength and therefore in the breakage of a surgical implant.