Osteosynthesis with pure titanium implants in foot and ankle surgery

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Outline

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«It was concluded that the current extent of exposure to titanium of the general population does not pose a health risk» (Hazardous Substances Data Bank – HSDB).

Pure titanium is used in dental implants since 1953. The pioneer in this matter is Professor PI Branemark from the University of Göteborg in Sweden. He gets a rate of osseous integration of 98%.

"At that time I happened to meet him and he indicated a new metal, titanium, from Russia used in nuclear industry, that might be optimal. I managed to get a sample from Russia via Avesta Jernverk, Director Gauffin, and from there on it has been pure Titanium. Initially we tried Tantalum, which was too soft.....

The commercial influence was a necessary step, but it is imperative, that requirements on new procedures, materials and interfaces are thoroughly examined in long term, multi clinical studies before released to general use"

THE IMPLANTS

Since almost 20 years (1988) we use TIT40 for osteosynthesis of the foot, in the form of asymmetric staples with diverse dimensions, and tutors with a sharp end. Their price is modest when compared to other titanium staples. These implants have a cylindrical diameter of 1.6 to 2.5 mm. The surface is treated with ultrasound in a bath with acetone to eliminate the contaminating agents on the surface which generate inflammatory reactions in vivo. Then they are shaped and anodised. (Fig 4) It is possible to replace the staples 3 or 4 times without compromising the strength of the construct if all is done carefully.

This is a major advantage in the midfoot and the forfoot where the volume of bone is limited. After impaction they hold on so tightly that the introducing clamp is needed for removal.

The elasticity of T40 is used to assure the interfragmentary compression. This is the case when the staples are introduced and advanced with diverting legs, with 1mm difference between the entry point and the final position.

PRINCIPLES OF OSTEOSYNTHESIS IN THE FOOT (1)

Neutralization of the separating forces on the bony fusion site (which inhibit bony healing), then stabilisation and compression of the bony fusion site.

The surface of the bony fusion site is very important to consider. In fact: the larger it is, the easier will be the bony healing (e.g., double spherical form technique ("male-female") when possible). The rougher the surface is with a reciprocal wedge, the more it opposes the separating and rotational forces. The cutting technique has to be chosen in order to avoid thermal injury to the bone. This often occurs when using saws and reamers oscillating at high speed without irrigation. Also try to avoid large unnecessary exposures who jeopardize the microcirculation (rather opt for multiple small approaches).

We can discuss several alternatives and link several methods.

The choice has to be made between a "stable" osteosynthesis as proposed by AO - which often needs extended approaches - and a functional orthopaedic method with a lighter form of osteosynthesis protected by a plaster cast (sole), changed or readjusted if needed, according to the reduction of the soft tissue swelling. In the postoperative setting plaster of Paris is preferred to a synthetic cast because of its moulding capacity and fluid absorption. This minimizes the risk of maceration and infection.

- Cannulated screws in TA6V titanium alloy better allow mini-invasive surgery. E.g. in the treatment of metatarsal fractures and anterior tarsal lesions one can easily combine percutaneous screws with temporary fixation with titanium pins and / or staples; even for a fracture of the os naviculare or talus.
- The staple can also be used to stabilise a gap filled by a bone graft, like an internal distractor. A suture can also easily be added for supplementary cerclage wiring.
- The titanium tutor can also reinforce a graft by allowing support, therefore producing a more resistant composite beam.

Bony healing with a hypertrophic callus due to insufficient immobilisation of the bony fusion site has to be avoided. This can be uncomfortable functionally and when weight bearing, but usually remodels as time goes by. Malunion and non union are most harmful for function, especially in the presence of an important fibrous scar due to the extensive exposure.

A plate with screws can result in a nice fixation with a nice x-ray, but at the expense of an extensive exposure and periostal stripping; risking hardware failure, non union, cutaneous complications and infection. An elastic fixation associated with a cast immobilisation is an option that better respects the soft tissues and the circulation.

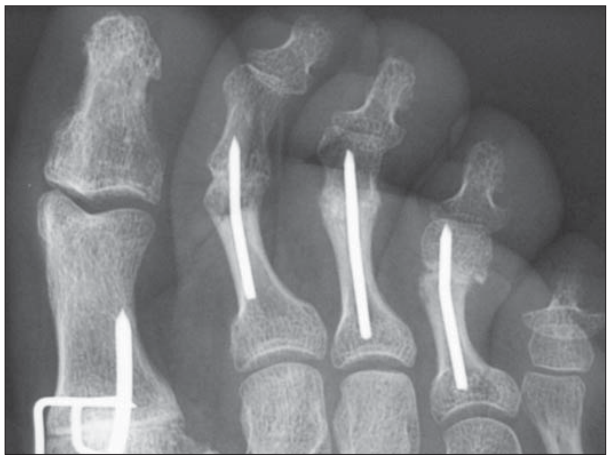
THE MAIN INDICATIONS FOR TIT40 IN ELECTIVE SURGERY OF THE FOOT ARE:

- PIP arthrodesis
- Hallux P1 osteotomy
- MTP1 arthrodesis
- Reconstruction-arthrodesis of the first ray with a composite graft
- Midfoot and hindfoot arthrodesis
- Ankle arthrodesis
- Tendon transfer fixation (one staple across at the end of a tunnel directly, or in U, allowing tensioning and fixation of the sutures)

We will only emphasize the results that are directly important here: i.e. bony union and complications.

PIP arthrodesis with TiT40

Simple technique with a dorsal longitudinal trans-tendon approach (transversal approach can also be used). P1 condyles are resected as needed, while paying attention to remain in cancellous bone. P2 Cartilage and subchondral bone are removed with a rongeur. The medullary canal is permeated. A piece of cylindrical 1.6 mm K-wire is calculated to be positioned as an in-lay tutor, by "va-et-vient" technique. Due to the moulding ability of T40 an angulation can be given as needed, to adjust and harmonise the position of the toe with respect to the adjoining toes. Finally the extensor tendon and the skin



are closed. The resulting forces impact the PIP-arthrodesis along the course of the tutor. The patient can immediately start weight bearing. The postoperative course is not very painful.

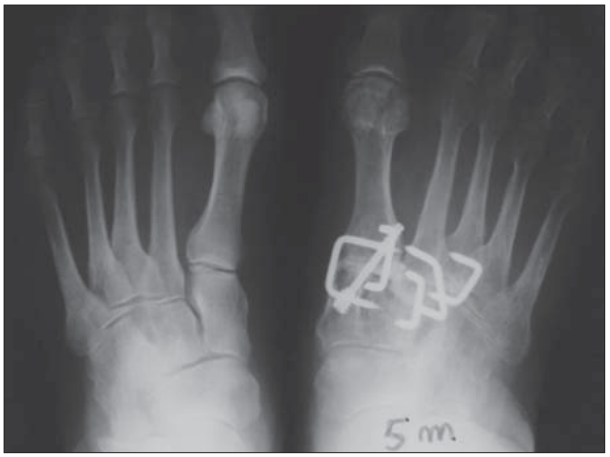
Complications

- no mechanical hardware failure
- no infection
- a few delayed unions and well tolerated non unions
- with important osteoporosis the tutor is exceptionally advanced through P2 and the dorsal skin, with partial reoccurrence of claw toe

One of the major advantages of pure titanium is its low susceptibility to infection. It will be lined by epithelial cells, making it easily removable in the outpatient clinic setting. If necessary, revision is relatively easy by a dorsal transosseous approach. The tutor is cut with wire cutters and retrieved with a strong needle holder by a rotating traction force.

Indications

- Isolated claw toes with important traction of the flexor tendons
- Certain congenital claw toe deformities



Courtesy JL Besse

- Claw toes in association with pathology a/the lesser ray(s)
- Painful unsuccesful arthroplasties. If too much bone was resected previously (floppy toes), it is sometimes necessary to supplement with an autograft to lengthen a toe.
- Neurological claw toe deformity, if necessary complemented with a lengthening of the flexor tendons (brevis to longus, technique according to Valtin) (19)
- Claw toe deformity after compartment syndrome

Phalanx osteotomy

In 500 osteotomies : no problems with bony healing : 100% union

- Infection : 0%
- Non union : 0%
- Delayed union : 8%
- Overcorrection with varus deformity : 4%
- Medial migration of the staple : 12,5%
- Secondary removal : 18 staples

Metatarsophalangeal-sesamoid arthrodesis of the hallux

- Bony union : 99,3% in a series of 272 primary arthrodesis cases
- Average time to union : 6 weeks (3 to 12)

Reconstruction - arthrodesis of the first ray with a composite graft : pure titanium T40 – bone

Poor skin and soft tissues condition, and often bad bone quality are encountered in these cases. The strength, elasticity, pliability,malleability, exceptionnal biologic tolérance of pure titanium implants associated with very rare infection are very useful.

Pure TIT40 implant are used in a composite beam mode wtih bone graft and titanium inlay

Hindfoot and midfoot arthrodesis with Lisfranc joint

This region is well known for its difficulty to obtain bony union. Its small bones with curved surfaces and the important forces acting on it render its fixation difficult. These arthrodeses implied non weight bearing for 6 weeks postoperatively, followed by progressive weight bearing, protected with a moulded orthosis.

In a series of 42 arthrodeses one non union was noted at the level of C2M2 (central Lisfranc). This means bony union in 97,5% cases.

Ankle arthrodesis

It is a technically demanding intervention: TIT40 implants can be used alone according to the axial tutor principle in combination with 2 or 3 2.5 staples in elastic compression. If the bone quality doesn't allow the use of classic screw fixation (osteoporosis, subchondral cysts, sclerotic brittle bone) and the use of an external fixator is to be avoided, titanium TIT40 implants remain the only possibility for internal fixation. They can also be combined with screw fixation or nailing to augment the rigidity and to control rotation. Cast immobilisation is recommended in all cases, without weight bearing for 5 weeks (only in the case of nailing where weight bearing can be allowed earlier)

INDICATIONS FOR TIT40 IN FOOT AND ANKLE TRAUMATOLOGY

- The exceptional properties of TIT40 make it possible to use staples or tutors for a number of osteosyntheses with minimal invasive or percutaneous approaches. If the tutors are used as K-wires it is imperative to predrill the cortex as the flexibility of titanium doesn't permit self drilling in normal or dense bone. However it is possible in osteoporotic bone.
- Fixation of epiphysis and metaphysis : direct stapling with elastic compression, cerclage wiring on long staples or tutors
- Fixation after reduction of a Lisfranc fracture – dislocation in particular
- Fixation of complex fractures with small osseous fragments which are impossible to fix with screws
- Temporarily syndesmosis fixation

It is advised to remove the implants once bony union is accomplished; in particular in the ankle, hindfoot and midfoot, because the osseous integration of titanium can rapidly complicate their removal, especially in the young patient.

CONCLUSION

TIT40 staples and tutors are easily produced with an acceptable price. They are easy to use, discrete and solid (and can even be tolerated in an infected environment). In the array of today's materials used for osteosynthesis they keep their place.

They represent the advantages of the **SAFE technique**: Simple, Atraumatic, Fast and Effective. Protection of the fixation with a moulded plaster cast is highly recommended.

Their limited artefact effects allows the use of CT-scan and MRI.

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