SciComm Bulletin

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Nobel Biocare cold-worked titanium

In conjunction with its development of TiUnite®, Nobel Biocare collaborated with titanium suppliers to create a dental implant material with exceptional material properties, without needing to alloy.[1]

Since being introduced to the market, following extensive material and pre-clinical testing, Nobel Biocare's proprietary, cold-worked, commercially pure titanium and patented TiUnite surface have been documented as exceptionally strong[2] and clinically proven to enhance osseointegration[3] (Glauser et al 2001).

Commercially pure standard titanium

Since his discovery of osseointegration, Prof PI Brånemark has prescribed commercially pure (c.p.) titanium[4] for use in dental implant restorations (Brånemark et al. 1985):

Key messages

- One of the most documented and preferred biocompatible materials:
  - Material of choice for dental implants (Steinemann 1998)
- Nobel Biocare has used c.p. titanium for more than 20 years

Properties

- Highly biocompatible (Donachie 1988)
- Excellent corrosion resistance (Donachie 1988)
- Very low rate of adverse biological reactions (Bardos 1990)
- Osseointegrates – integrates with living bone (Brånemark et al 1985)

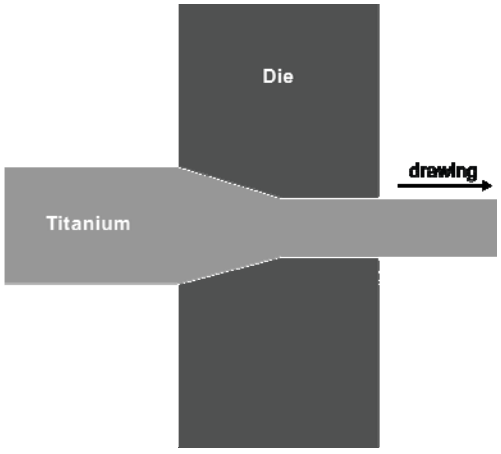
Noble Biocare cold-worked titanium

Nobel Biocare commemorates the tenth year of using its high-performance titanium for its entire dental implant offering, which includes small diameters (Ø < 3.5 mm):

Key messages

- Ten years of pre-clinical and clinical use
- Proprietary cold-working (strengthening) process:
  - Significant gains in material strengths: yield, tensile and device fatigue
  - No need to sacrifice material purity through alloying[1]
- Resolved material limitations of standard titanium for use with small diameter implants[5]
- Purity and strength confirmed in ongoing external material supplier and internal implant lot testing[2]

Cold-working process



- At a specific temperature and drawing rate, titanium is deformed in a die, resulting in material strain hardening (Donachie 1988)

[1] Alloying introduces elements that potentially cause adverse biological effects and can increase risk of fracture (elongation fracture)
[2] External material and internal implant lot testing confirms gains in material properties, data on file
[3] Compared to implants with machined surfaces
[4] According to the American Society for Testing and Materials specification, ASTM F67
[5] Internal warranty system tracking NobelDirect 3.0 mm implants, data on file

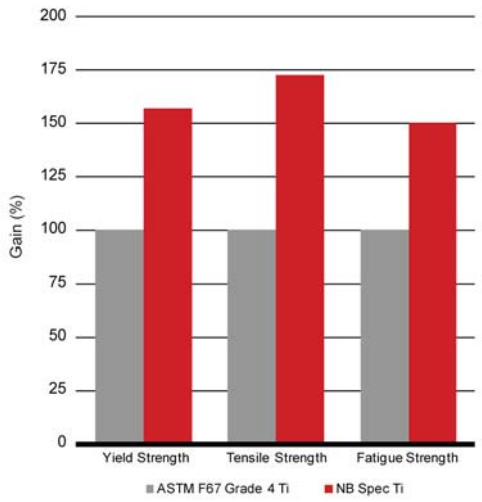
Substantial gains in titanium strength

Nobel Biocare's proprietary, cold-working process produces c.p. titanium with significant gains in material strengths:

Key messages

- Yield strength >55%
- Tensile strength (min.) >70%
- Device fatigue strength >50%

Evidence



- Ongoing external material and internal implant lot testing confirms gains in material properties[6]

Small diameter implant success

Nobel Biocare cold-worked titanium delivers excellent device fatigue strength and performance in small diameter implants (Ø < 3.5 mm):

Key messages

- Nine years of small implant experience
- No fatigue fracture for small diameter implants:[7]
  - Effectively negates the need for a stronger material
- Small diameter implants:
  - Offer less invasive dental implant solutions for patients with narrow bone ridges, and limited space between teeth
  - Can minimize the need for guided bone regeneration (GBR) procedures
- Small diameter, one-piece implants are designed for restorations with exceptionally steep emergence angles for excellent final esthetics

Facts

- Two-piece implant, launched in 2000:
  - Brånemark System Mk III Ø3.3 mm
- One-piece implant, launched in 2004:
  - NobelDirect Ø3.0 mm

[6] Data on file
[7] Internal warranty system tracking NobelDirect 3.0 mm implants, data on file

References

Bardos DI. Titanium and Titanium Alloys: Medical and Dental Materials (Williams D ed.) Pergamon Press 1990:360-5.

Brånemark PI, Zarb GA, Albrektsson T, ed. Tissue-integrated prostheses: osseo-integration in clinical dentistry. Quintessence Publishers, Carol Stream IL, 1985:11-76, 129-143.

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Glauser R, Portmann M, Ruhstaller P, Lundgren AK, Hämmerle C, Gottlow J. Stability measurements of immediately loaded machined and oxidized implants in the posterior maxilla. A comparative clinical study using resonance frequency analysis. Appl Osseointegration Res 2001;2:27-9.

Steinemann SG. Titanium – the material of choice? Periodontology 2000 1998;17:7-21.