Quality of Dental Implants

Asbjørn Jokstad
University of Toronto
Situation, end of 90’ies

The number of implants and implant systems increase continuously.
FDI is concerned about the quality of all the new implants being marketed.
FDI Science Committee commissioned a project to investigate the issue.
What characterizes a good quality implant? When...

- there are clinical data over 3 ... 5 ... 10yrs?
- implant is made from cpTi grade 1 ... 3 ... 4?
- implant is rough .. etched .. groovy ... rounded ... connects internally ... sandblasted ... ?
- the producer follows an ISO9001 standard?
- a well known researcher tells you so?
- a well known clinician tells you so?
- your sales rep tells you so?
- scientific clinical studies provide an answer?
Scientific studies with similar aims:


Scientific studies with similar aims:


Interventions for replacing missing teeth with or without osseointegrated implants [protocol]

Reviewer(s)

<table>
<thead>
<tr>
<th>Reviewer(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esposito M, Coulthard P, Worthington HV, Thomsen P</td>
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Contribution of Reviewer(s)

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<tbody>
<tr>
<td>Paul Coulthard - data collection, assessment and analysis and final review</td>
</tr>
<tr>
<td>Marco Esposito - data collection, assessment and analysis and final review</td>
</tr>
<tr>
<td>Asbjorn Jokstad - data collection, assessment and analysis and final review</td>
</tr>
<tr>
<td>Helen Worthington - statistical analysis and final review</td>
</tr>
<tr>
<td>Peter Thomson - final review</td>
</tr>
</tbody>
</table>

Background

Missing teeth and support for masticatory, phonetic function have been shown to improve life quality. The osseointegration concept, termed osseointegrated implant retained prostheses, was developed in Sweden over 10 years ago and has received widespread and well-accepted use in dentistry over the past 20 years. A multitooth implant retained prosthesis is a major development in prosthodontic therapy.
Since 2000: 10 systematic reviews completed on osseointegrated dental implants

Esposito M, Coulthard P, Worthington H, Thomson P / (Jokstad A)

Problem: Selection of studies to include
<table>
<thead>
<tr>
<th></th>
<th>Cochrane systematic reviews:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Zygomatic implants</td>
</tr>
<tr>
<td>2.</td>
<td>Hyperbaric oxygen therapy</td>
</tr>
<tr>
<td>3.</td>
<td>Use of prophylactic antibiotics</td>
</tr>
<tr>
<td>4.</td>
<td>Perimplantitis</td>
</tr>
<tr>
<td>5.</td>
<td>Preprosthetic surgery vs implants</td>
</tr>
<tr>
<td>6.</td>
<td>Bone augmentation techniques</td>
</tr>
<tr>
<td>7.</td>
<td>Surgical techniques</td>
</tr>
<tr>
<td>8.</td>
<td>Immediate or conventional loading</td>
</tr>
<tr>
<td>9.</td>
<td>Maintenance</td>
</tr>
<tr>
<td>10.</td>
<td>Characteristics of implants</td>
</tr>
</tbody>
</table>
The quality of RCTs of oral implants is generally poor and needs to be improved.
Materials and methods

1. **PICO:**

<table>
<thead>
<tr>
<th>Problem: Claims of superiority</th>
<th>Intervention: Implant characteristic (material, geometry, surface topography)</th>
<th>Comparison: Implant without characteristic</th>
<th>Outcomes: Clinical relevant &amp; Clinical significant</th>
</tr>
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Materials and methods

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</table>

**All types of information sources:**

**Scientific & quasi-scientific literature, WWW, promotional brochures and leaflets, CD/DVDs, trade exhibitions, etc.**
Materials and methods

All information sources:

*Brochures, trade exhibitions, WWW, leaflets, presentations, etc.*

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Materials and methods

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</tbody>
</table>
Differences in implant material:

- **C.p.1 Titanium** (e.g. Nobel Biopharma)
- **C.p.2 Titanium**
- **C.p.3 Titanium** (e.g. Straumann)
- **C.p.4 Titanium** (e.g. AstraTech)
- **Titanium-alloys** (e.g. C.p.5: Ti-6Al-4V)
- **Hydroxyapatite**
- ....
Differences in implant body geometry:

- Major morphological form
- Flange design
- Main body w/ wo/ threads
- Apex form, grooves & vents
- Interface geometry
- Surface topography
Straight, Tapered, Conical, Ovoid, Trapezoidal, Stepped & combinations …
Flange design

- Flange vs. no flange
- Straight vs. flared vs. widening
- Height
- Polished vs. threads
- Added features
- Surface topography
• Threads vs. non-threads
• Shape: V- vs. square- vs. reverse buttress- vs. combinations
• Number and size of “lead threads”
• Number and location of grooves, groove forms and groove sizes
• Surface micro-topography
• Thread angle
Apex
• Threaded vs non-threaded
• V-shape vs flat vs curved apex
• Holes, round, oblong
• Apical chamber
• Grooves and groove size
• Flared apex
• Surface topography
Interface geometry

- External vs Internal
- Hexagonal vs Octagonal vs cone
- Morse taper
- Rotational vs non-rotational
- Added non-rotational features
- Heights & widths
- Butt vs bevel joints
- Slip-fit vs friction-fit joints
- Resilience vs nonresilience
<table>
<thead>
<tr>
<th>Surface topography</th>
<th>Machining process</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anisotropic with oriented cutting marks</td>
<td>Turned</td>
<td>Brånemark System® MKIII (Nobel Biocare)</td>
</tr>
<tr>
<td>Isotropic</td>
<td>Blasted</td>
<td>TiO2 particles (Tioblast®, AstraTech)</td>
</tr>
<tr>
<td>Isotropic</td>
<td>Blasted + acid etched</td>
<td>1. Large size Al2O3 particles &amp; HCl &amp; H2SO4 (SLA®, Straumann) - 2. Tricalcium phosphate &amp; HF &amp; NO3 (MTX®, Centerpulse)</td>
</tr>
<tr>
<td>Isotropic with high frequency irregularities</td>
<td>Acid etched</td>
<td>HCl / H2SO4 (Osseotite®, 3i)</td>
</tr>
<tr>
<td>Isotropic and rough</td>
<td>Hydroxyapatite coated</td>
<td>Sustain® (Lifecore)</td>
</tr>
<tr>
<td>Isotropic and rough</td>
<td>Titanium Plasma Sprayed</td>
<td>ITI® TPS (Straumann)</td>
</tr>
<tr>
<td>Isotropic with craterous structure</td>
<td>Oxidized</td>
<td>TiUnite® (Nobel Biocare)</td>
</tr>
</tbody>
</table>
Materials and methods

All information sources:
Brochures, trade exhibitions, WWW, leaflets, presentations, etc.

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Claims of improved clinical outcomes

1. Ease of placement
2. Osseointegration
3. Esthetics
4. Peri-implant mucositis
5. Marginal bone loss
6. Mechanical problems of the implant-abutment-superstructure connections
7. Mechanical failing of dental implants
Materials and methods

1. PICO: Comparative elements
2. Information presented by manufacturers
3. Evidence in the scientific literature
   - Category A1, clinically controlled trial with patient randomization (RCT)
   - Category A2, clinically controlled trial with split-mouth randomization, (Split-mouth RCT)
   - Category B, (prospective) clinically controlled trial without randomization (CCT)
   - Category C, clinical study applying any other study design than A or B (e.g. retrospective cohort, case-series, case-controls, etc.).

Cochrane, ISI, Medline, Embase, IADR abst., etc
Results

N=1270
Commercially available implant and implant systems in October 2003:

225 implant brands
78 manufacturers – from all continents
~70 implant brands no longer marketed
Clinical documentation:
from none to extensive
126 clinical studies related outcome to implant characteristics (material, geometry, surface topography)

<table>
<thead>
<tr>
<th></th>
<th>RCTs</th>
<th>CCTs</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ease of placement</td>
<td>4</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2. Osseointegration</td>
<td>25</td>
<td>3</td>
<td>21</td>
</tr>
<tr>
<td>3. Esthetics</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4. Peri-implant mucositis</td>
<td>21</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>5. Marginal bone loss</td>
<td>19</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>6. Mechanical problems</td>
<td>6</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>of the implant- abutment-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>superstructure connection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Mechanical failing of</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>dental implant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>77</td>
<td>15</td>
<td>34</td>
</tr>
</tbody>
</table>
### 126 clinical studies related outcome to implant characteristics (material, geometry, surface topography)

<table>
<thead>
<tr>
<th></th>
<th>RCTs</th>
<th>CCTs</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Ease of placement</strong></td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td><strong>2. Osseointegration</strong></td>
<td>25</td>
<td>3</td>
<td>21</td>
<td>49</td>
</tr>
<tr>
<td>3. Esthetics</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>4. Peri-implant mucositis</td>
<td>21</td>
<td>0</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>5. Marginal bone loss</td>
<td>19</td>
<td>6</td>
<td>2</td>
<td>27</td>
</tr>
<tr>
<td>6. Mechanical problems of the implant- abutment-superstructure connection</td>
<td>6</td>
<td>1</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>7. Mechanical failing of dental implant</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>77</td>
<td>15</td>
<td>34</td>
<td>126</td>
</tr>
</tbody>
</table>
49 clinical studies related a specific implant characteristic to the outcome: **osseointegration**

<table>
<thead>
<tr>
<th>Embedding</th>
<th>RCTs</th>
<th>CCTs</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant geometry</td>
<td>4</td>
<td>-</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>Implant material</td>
<td>3</td>
<td>-</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Implant surface</td>
<td>5</td>
<td>-</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Complex study design</td>
<td>13</td>
<td>3</td>
<td>10</td>
<td>26</td>
</tr>
</tbody>
</table>

25 | 3 | 21 | 49
Has this report led to anything?
Quality of Dental Implants

Background
More than 220 implant brands produced by about 80 manufacturers are commercially available worldwide. These are made from different materials, undergo different surface treatments and manifest in different shapes, lengths, widths and forms. The clinician can in theory choose among more than 2000 implants.

FDI recognizes that:

- Implants made from titanium and titanium alloys appear to perform well clinically in properly surgically prepared bone, regardless of small variations in design.

- The scientific evidence of the influence of dental implant material, geometry and surface topography on their clinical performance is limited and the study methodology is not strong. Hence there is inconclusive evidence for promoting specific implants or implant systems over others.

- Implants are manufactured and sold in some parts of the world without compliance to international standards.

It would seem prudent to only use dental implants supported by sound clinical research documentation and which conform to the general principles of good manufacturing practice in compliance with the ISO Standards or FDA (Food and Drug Administration) and other regulatory bodies.

- Most clinical trials on dental implants focus on criteria relative to peri-implant aspects over relatively short observation periods. Such criteria are only surrogate measures for treatment outcome from the patient and general public perspectives.

Submitted by: FDI Science Committee

Adopted by the FDI General Assembly
12th September 2004 – New Delhi
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Submitted by: FDI Science Committee
Implant Manufacturers

A part of the FDI Science Commission Project 98-5 titled "Quality of Dental Implants" is to present this continuously updated list of implant manufacturers worldwide. The full report is published as a separate supplement to the International Dental Journal: Jokstad A, Braegger U, Brunski JB, Carr AB, Naert I, Wennerberg A. Quality of Dental Implants. Int Dent J, 2003; 53 Supplement 2: 409-33.

Please click on the link below to launch the list.

- Implant Manufacturers
Jokstad, Brägger, Brunski, Carr, Naert, Wennerberg.

*Int Dent J* 2003; 53 Sup 2: 409-33

&

*Int J Prosthodont* 2004; 17: 607-41
The "Groovy implant"

Feeling Groovy

In 2005, Nobel Biocare took the complete range of TiUnite® implants to a new level of effectiveness with the introduction of the Groovy™ technology. As a further step towards shorter healing times and safer implant treatment, Nobel Biocare added a groove of optimal dimensions to the thread of the implants. The combined effect of TiUnite® and the groove is a favorable environment that stimulates faster bone growth within and along the groove. The result is not only further enhancement of the rate of osseointegration, but also up to 30 percent higher implant stability due to increased mechanical interlock between the bone and the implant.

Benefits of Grooves Incorporated onto the Thread of the Implant:

- Up to 30 percent higher stability
- Enhanced osseoconductive properties leading to higher biomechanical stability
- Bone forms more rapidly along the grooves compared to the rest of the implant
- Particularly effective in soft bone

> GROOVY IMPLANT
The groove at the thread takes the TiUnite® implants to a new level of effectiveness.

> GROOVY BONE FORMATION
Faster bone growth within the groove results in enhanced rate of osseointegration and biomechanical stability.
# 1.4 510(k) Summary of Safety and Effectiveness

| Submitted by:                      | Herbert Crane  
|------------------------------------|----------------|
| Address:                           | Nobel Biocare USA LLC  
|                                    | 22715 Savi Ranch Parkway 
|                                    | Yorba Linda, CA 92887  
| Telephone:                         | (714) 282-4800, ext. 7830  
| Facsimile:                         | (714) 282-9023  
| Date of Submission:                | February 2, 2005  
| Classification Name:               | Endosseous Implant (21 CFR 872.3640)  
| Trade or Proprietary or Model Name:| Groovy Implants  
| Legally Marketed Device(s):        | Nobel Biocare Endosseous Implants (K041661)  

2.Feb 2005: 510K Application
Indications for Use:
Nobel Biocare’s Groovy Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare’s Groovy Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare Groovy Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

Groovy implants are indicated for use in soft bone in posterior regions or whenever immediate or early stability is desired. This Groovy Implant forms bone more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants.
Purpose: Study if bone formation and implant stability were influenced by 110 μm and 200 μm and 70 μm deep grooves positioned at a thread flank

M&M: 18 rabbits – 6 x 7 mm implants
9: 3 control impl. + 3 test impl. (110 μm wide & 70μm deep)
9: 3 control impl. + 3 test impl. (200 μm wide & 70μm deep)
6 weeks → Removal torque (RTQ) (2 control impl. vs 2 test impl.)
→ Histology (1 control impl. vs 1 test impl.) “bone-fill”

Results:

<table>
<thead>
<tr>
<th>Groove Width</th>
<th>RTQ</th>
<th>% Bonefill</th>
<th>p-value</th>
<th>vs. Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>110x70 μm</td>
<td>+30%</td>
<td>p&lt; 0.05 (36)</td>
<td>p&lt; 0.05 (18)</td>
<td>vs. control</td>
</tr>
<tr>
<td>200x70 μm</td>
<td>+8%</td>
<td>p&lt; 0.05 (36)</td>
<td>p&lt; 0.05 (18)</td>
<td>vs. control</td>
</tr>
</tbody>
</table>

Conclusion: “The 110 micron-wide groove was shown to increase the resistance to shear forces significantly. It is suggested that implants with such a groove may be one way to optimize implant stability in suboptimal clinical conditions.”
DEPARTMENT OF HEALTH & HUMAN SERVICES

Nobel Biocare AB
C/O Mr. Herbert Crane
Manager, Regulatory Affairs
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

APR 19 2005

Re: K050258
Trade/Device Name: Groovy Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: February 2, 2005
Received: February 3, 2005

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.
2 Feb 2005: Application
19 April 2005: Approval
6 June 2005: World Premiere!

MGM Arena, Las Vegas
“Welcome to Dentium Dental Implant System: Since the establishment of Dentium in the USA in 2004, we have been manufacturing high quality dental implant products. Our extensive clinical documentation and research have lead to the development of an innovative, simple, and versatile dental implant system...”
New implants since Oct 2003:

The REVOIS Implant – the Star

Willkommen bei Z-Systems

World’s first certified
Dental Zirconiumoxide Implants

PHI Primary Healing Implant™
Thank you for your kind attention