Quality of Denta mplants

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:

- Eckert et al. Validation of dental implant systems through a review of literature supplied by system manufacturers. J Prosthet Dent 1997;77: 271-9.
- Esposito et al. Interventions for replacing missing teeth: different types of dental implants. Cochrane Database Syst Rev 2002;(4). (version 1)
- Jokstad et al. Quality of dental implants. Int Dent J 2003;53 (6 Suppl 2): 409-43.

Eckert et al. Comparison of dental implant systems: quality of clinical evidence and prediction of 5year survival. Int J Oral Maxillofac Impl 2005; 20: 406-15.

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

			1
This protocol should	Reviewer(s)	Esposito M, Coulthard P, Worthington HV, Thomsen P	or rontocino missino
teeth with or without	Contribution of Reviewer(s)	Paul Coulthard - data collection, assessment and analysis and final review Marco Esposito - data collection, assessment and	or replacing missing vary, Issue 1, 2001.
Background [Missing teeth and supp masticatory, phonetic f showing that bone will concept, termed osseo past 20 years. A multit implant retained prosth		analysis and final review Asbjorn Jokstad - data collection, assessment and analysis and final review Helen Worthington - statistical analysis and final review Peter Thomson - final review	ig restoration of over 10 years 'ell-accepted s in dentistry over the osseointegrated
S Docu	Issue protocol first published	2000 Issue 3	
	Date of most recent amendment	30 August 2000	

Cochrane Oral Health Group

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

Cochrane systematic reviews: (Coulthard / Esposito & Worthington) 1. Zygomatic implants 0 RCT 2. Hyperbaric oxygen therapy 0 RCT 3. Use of prophylactic antibiotics 0 RCT 4. Perimplantitis 1 RCT 1 RCT Preprosthetic surgery vs implants Bone augmentation techniques 4 RCTs . Surgical techniques 4 RCTs . Immediate or conventional loading 5 RCT **5 RCTs** Maintenance 0. Characteristics of implants 12 RCTs



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Jokstad, Brägger, Brunski, Carr, Naert, Wennerberg. *Int Dent J 2003;* 53 Sup 2: 409-33

Asbjørn Jokstad, Oslo, Norway Urs Braegger, Bern, Switzerland John B. Brunski, Troy, USA Alan B. Carr, Rochester, USA Ignace Naert, Leuven, Belgium Ann Wennerberg, Gothenburg, Sweden International Dental Journal





Quality of Dental Implants



<u>1. PICO:</u>

Problem:	Intervention	Comparison	Outcomes
Claims of superiority	Implant characteristic (material, geometry, surface topography)	Implant without characteristic	Clinical relevant & Clinical significant

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All types of information sources:

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

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TITANIUM ALLOY FOR STRENGTH (SBM SURFACE)

www.implantdirect.com

CP TITANIUM WITH *TIUNITE SURFACE (Alloy on HA)

ce Select and TiUnite are Trademarks of N

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PICO:

Problem:	Intervention	Comparison	Outcomes
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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-6AI-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 nonthreaded
- 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 nonrotational
- Added nonrotational features
- Heights & widths
- Butt vs bevel joints
- Slip-fit vs friction-fit joints
- Resilience vs
 nonresilience

Surface topography	Machining process	Example
Anisotropic with oriented cutting marks	Turned	Brånemark System® MKIII (Nobel Biocare)
Isotropic	Blasted	TiO2 particles (Tioblast®, AstraTech)
Isotropic	Blasted + acid etched	1. Large size Al2O3 particles & HCl & H2SO4 (SLA®, Straumann) - 2. Tricalcium phosphate & HF & NO3 (MTX®, Centerpulse)
Isotropic with high frequency irregularities	Acid etched	HCl / H2SO4 (Osseotite®, 3i)
Isotropic and rough	Hydroxyapatite coated	Sustain® (Lifecore)
Isotropic and rough	Titanium Plasma Sprayed	ITI® TPS (Straumann)
Isotropic with craterous structure	Oxidized	TiUnite® (Nobel Biocare)

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PICO:

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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 implantabutment-superstructure connections
- 7. Mechanical failing of dental implants

- 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 splitmouth 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.).

<u>Cochrane, ISI, Medline, Embase, IADR abst.,etc</u>

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)

	RCTs	CCTs	Other	
1. Ease of placement	4	3	0	7
2. Osseointegration	25	3	21	49
3. Esthetics	1	1	0	2
4. Peri-implant mucositis	21	0	3	24
5. Marginal bone loss	19	6	2	27
6. Mechanical problems of the implant- abutment- superstructure connection	6	1	6	13
7. Mechanical failing of dental implant	1	1	2	4
	77	15	34	126

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49 clinical studies related a specific implant characteristic to the outcome: <u>osseointegration</u>

	RCTs	CCTs	Other	
Implant geometry	4	-	8	12
Implant material	3	-	2	5
Implant surface	5	-	1	6
Complex study design	13	3	10	26
	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

Reference: FDI Science Committee Project 5-98: Jokstad A, Brägger U, Brunski JB, Carr AB, Naert I, Wennerberg A. Quality of Dental Implants. *International Dental Journal*, 2003; 53: Suppl 3:409-443.

> Adopted by the FDI General Assembly 12th September 2004 – New Delhi

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Manufacturers	
Implant	
Dental Schools	
Continuing Education	
Publications	
Facts and Figures	
Guidelines	

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

FDI WORLD DENTAL FEDERATION, 13 CHEMIN DU LEVANT, L' CENTRE, F-01210 FERNEY-VOLTAIRE, FRANCE Disclaimer

-

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



> GP_OVY IMPLANT Degroove at the thread takes the TiUnite® plants to a new level of effectiveness.



30%

> ERCOVE BONE FORMATION Faster bone growth within the groove results in enhanced rate of osseointegration and biomechanical stability.

Page 33. In: Nobel Biocare. Annual report 2005



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 iaw 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

...bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to nongrooved implants.





way to optimize implant buomly in buooptima emical contaitons.

Public Health Service

9200 Corporate Boulevard Rockville MD 20850





19. April 2005: 510K Approval

APR 1 9 2005



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

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.

Mandal Managine Marriel California and Party

Coronal Ridge Reconstruction

Labial soft tissue support Pupillae support Scalioped shape Emergence profile Color, texture of 20th tissue



2 Feb 2005: Application

19 April 2005: Approval

6 June 2005:

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Thank you for your kind attention