Quality of Dental Implants

Asbjørn Jokstad
University of Toronto

Situation, 1999

1. The number of implants and implant systems increase continuously worldwide
2. The FDI World Dental Federation is concerned about the quality of all the new implants being marketed
3. The FDI Science Committee is asked to investigate the issue
4. The work is commissioned to prof. A Jokstad

How many implant brands/ systems were available in North America in 1999?

A: approx. 30

B: approx. 50

C: approx. 70

D: approx. 90

E: approx. 110

REVIEW ARTICLE

Implants and Components: Entering the New Millennium

Paul P. Binon, DDS, MSD[1]

The elusive dream of replacing missing teeth with artificial analogs has been part of dentistry for a thousand years. The coincidental discovery by Dr P-I Brånemark and his coworkers of the tenacious affinity between living bone and titanium oxides, termed *osseointegration*, propelled dentistry into a new age of reconstructive dentistry.

Initially, the essential tenets for obtaining osseointegration dictated the atraumatic placement of a titanium screw into viable bone and a prolonged undisturbed, submerged healing period. By definition, this required a 2-stage surgical procedure. To comply, a coupling mechanism for implant placement and the eventual attachment of a transmucosal extension for restoration was explored. The initial coronal design selected was a 0.7-mm-tall external hexagon. At its inception, the design made perfect sense, because it permitted engagement of a torque transfer coupling device (fixture mount) during the replacement, maxillofacial and a myriad of other applications, limited only by the ingenuity and skill of the clinician.[11-13] The external hexagonal design, ad modum Brånemark, originally intended as a coupling and rotational torque transfer mechanism, consequently evolved by necessity into a prosthetic indexing and antirotational mechanism.[14,15] The expanded utilization of the hexagonal resulted in a number of significant clinical complications.[8-11,16-22] To mitigate these problems, the external hexagonal, its transmucosal connections, and their retaining screws have undergone a number of modifications.[23]

In 1992, English published an overview of the then-available external hexagonal implants, numbering 23 different implants, all having the standard Brånemark hex configuration.[24] The external hex has since been modified and is now available in heights of 0.7, 0.9, 1.0, and 1.2 mm and with flat-to-flat widths of 2.0, 2.4, 2.7, 3.0, 3.4, and 3.4 mm.

Binon, IJOMI, 2000, 15(1): 76-95

Review of existing literature

Eckert S et al. Validation of dental implant systems through a review of literature supplied by system manufacturers. J Prosthet Dent 1997;77: 271-9.

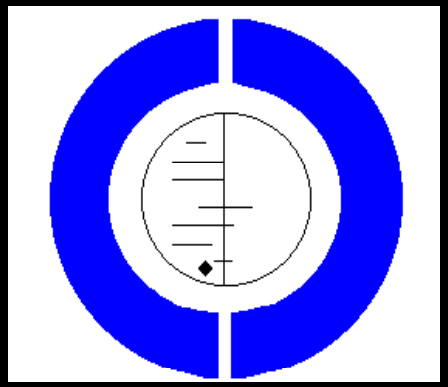
Conclusion:

On the basis of the literature supplied by the manufacturers, only one implant system demonstrated scientifically valid long-term success.

Scientific studies with similar aims:

Eckert et al. J Prosthet Dent 1997; 77: 271-9.

The International Cochrane Collaboration?



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

Reviewer(s)	Esposito M, Coulthard P, Worthington HV, Thomsen P
Contribution of Reviewer(s)	Paul Coulthard - data collection, assessment and analysis and final review Marco Esposito - data collection, assessment and 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
Issue protocol first published	2000 Issue 3
Date of most recent amendment	30 August 2000
Date of most recent	09 February 2000

This protocol should b
teeth with or without o

ıs for replacing missing
ibrary, Issue 1, 2001.

Background

Missing teeth and suppo
masticatory, phonetic fu
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ughs in dentistry over the
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Scientific studies with similar aims:

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Esposito M, Coulthard P, Worthington HE, Jokstad A. Interventions for replacing missing teeth: different types of dental implants. Cochrane Database Syst Rev 2002;(4). (1st version)

Benefits of Cochrane Systematic Reviews

- High internal validity
- Minimum bias
- Exhaustive bibliographic search

Problems of Cochrane Systematic Reviews

Benefits

- High internal validity
- Minimum bias
- Exhaustive bibliographic search

Problems

- If limited only to RCTs
-
-
- Low external validity – applicability?

Cochrane Oral Health Group

Since 2000: 11 systematic reviews completed on osseointegrated dental implants

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

Cochrane systematic reviews since 2000:

1. Zygomatic implants	0 RCT
2. Hyperbaric oxygen therapy	0 RCT
3. Use of prophylactic antibiotics	0 RCT
4. Perimplantitis	1 RCT
5. Preprosthetic surgery vs implants	1 RCT
6. Bone augmentation techniques	4 RCTs
7. Surgical techniques	4 RCTs
8. Immediate or conventional loading	5 RCTs
9. Maintenance	5 RCTs
10. Characteristics of implants	12 RCTs

Problems of Cochrane Systematic Reviews

Benefits

- High internal validity
- Minimum bias
- Exhaustive bibliographic search

Problems

- If limited only to RCTs
- If RCT are of poor quality
-
- Low external validity – applicability?

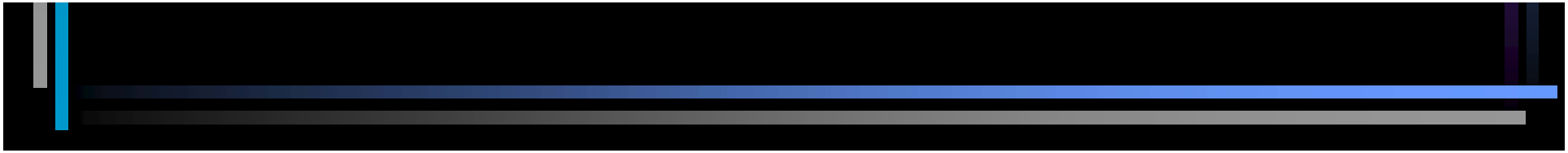
Quality Assessment of Randomized Controlled Trials of Oral Implants

Marco Esposito, DDS, PhD[1]/Paul Coulthard, BDS, MFGDP, MDS, FDSRCS, PhD[2]/
Helen V. Worthington, BSc, MSc, PhD, FIS[3]/Asbjørn Jokstad, DDS, PhD[4]

The aim of this study was to assess the quality of randomized controlled trials (RCTs) concerned with the effectiveness of oral implants and to create a trial register. A multilayered search strategy was used to identify all RCTs published by the end of 1999 in any language. The Cochrane Oral Health Group specialist register, PubMed, and personal libraries were searched. Seventy-four RCTs were identified. Forty-three articles, not presenting the same patient material, were independently assessed by 3 researchers using a specially designed form. A statistician assessed all trials for the appropriateness of statistics. The quality of each study was assessed on 7 items, including 3 key domains. Randomiza-

Esposito et al., Int J Oral Maxillofac Implants 2001; 16: 783-92

Key words: *dental implants, randomized controlled trial, registries, research design, review literature*



Quality assessment of RCTs

1) Was a sample size calculation undertaken?
2) Randomization and allocation concealment method described?
3) Were inclusion/exclusion criteria clearly defined?
4) Was reason for withdrawal specified by study group?
5) Were the control and treatment groups comparable at entry for important prognostic factors?
6) Was there any attempt at blinding (for example, independent assessor)?
7) Was the statistical analysis appropriate?

Methodological scoring of RCTs on dental implants – how do they score on a range from 1(poor) to 12(excellent)?

A: average 2

B: average 4

C: average 6

D: average 8

E: average 10

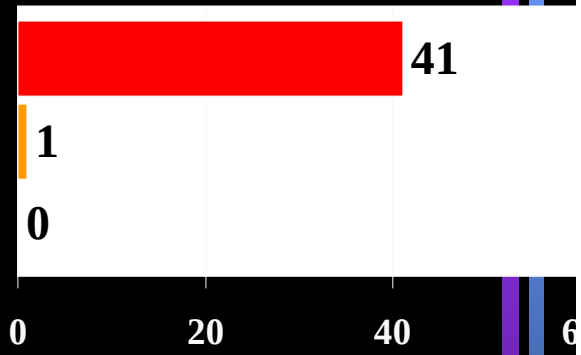
Implant RCTs- Quality assessment

A) Was a sample size calculation undertaken?

0 No/not mentioned

1 Yes, but not confirmed by calculation

2 Yes, confirmed



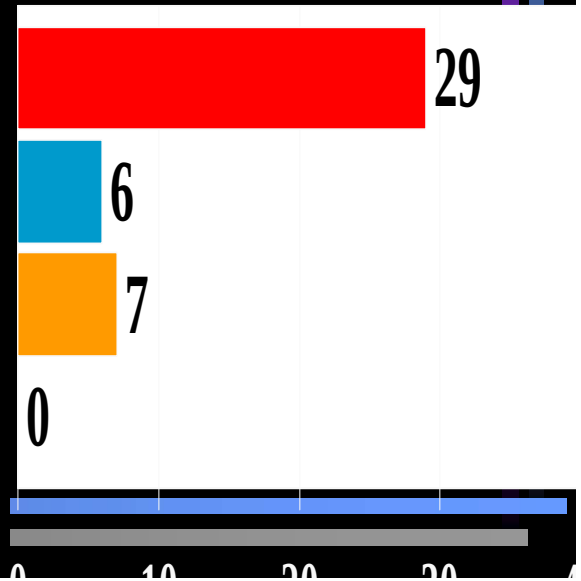
B) Randomization and allocation concealment method

0 Not described

1 Clearly inadequate - transparent before assignment

2 Possibly adequate-sealed envelopes

3 Clearly adequate- centralized randomization and third party contact for group code



Implant RCTs- Quality assessment

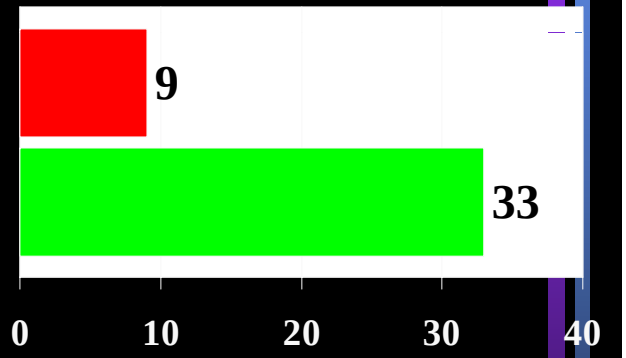
A) Was a sample size calculation undertaken?

B) Randomization and allocation concealment method

C) Were inclusion/exclusion criteria clearly defined?

0 No

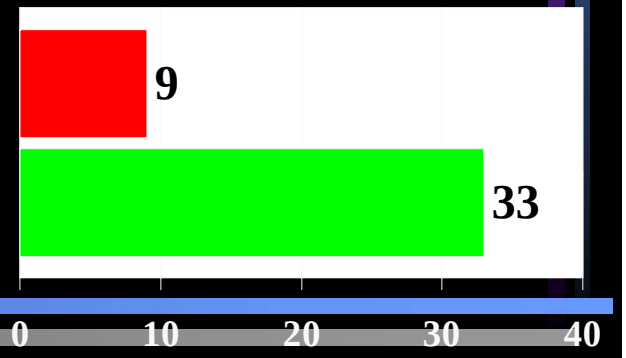
1 Yes



D) Was reason for withdrawal specified by study group?

0 No/not mentioned

1 Yes, or not applicable as no withdrawals

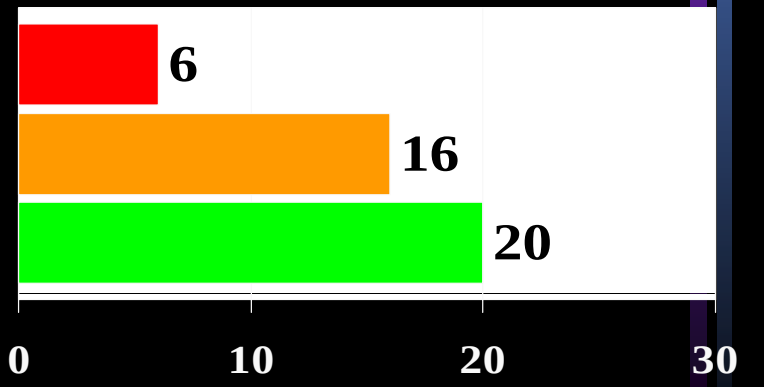


Implant RCTs- Quality assessment

A) Was a sample size calculation undertaken?
B) Randomization and allocation concealment method
C) Were inclusion/exclusion criteria clearly defined?
D) Was reason for withdrawal specified by study group?

E) Were the control and treatment groups comparable at entry for important prognostic factors?

0 No
1 Unclear
2 Yes

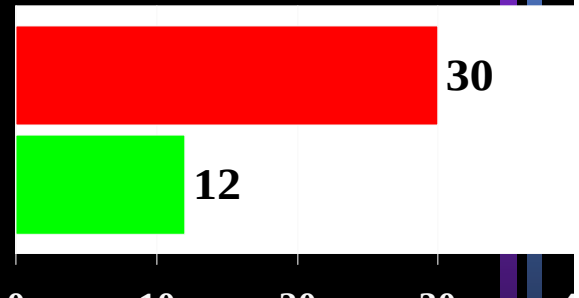


Implant RCTs- Quality assessment

A) Was a sample size calculation undertaken?
B) Randomization and allocation concealment method
C) Were inclusion/exclusion criteria clearly defined?
D) Was reason for withdrawal specified by study group?
E) Were the control and treatment groups comparable at entry for important prognostic factors?

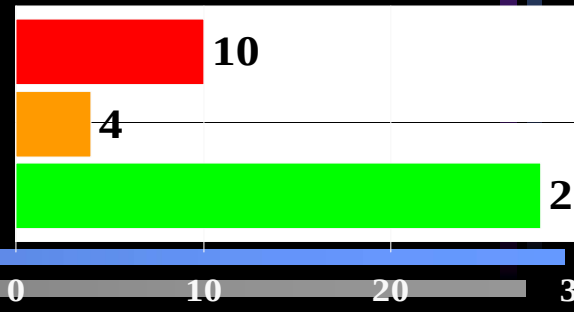
F) Was there any attempt at blinding (for example, independent assessor)?

0 No
1 Yes

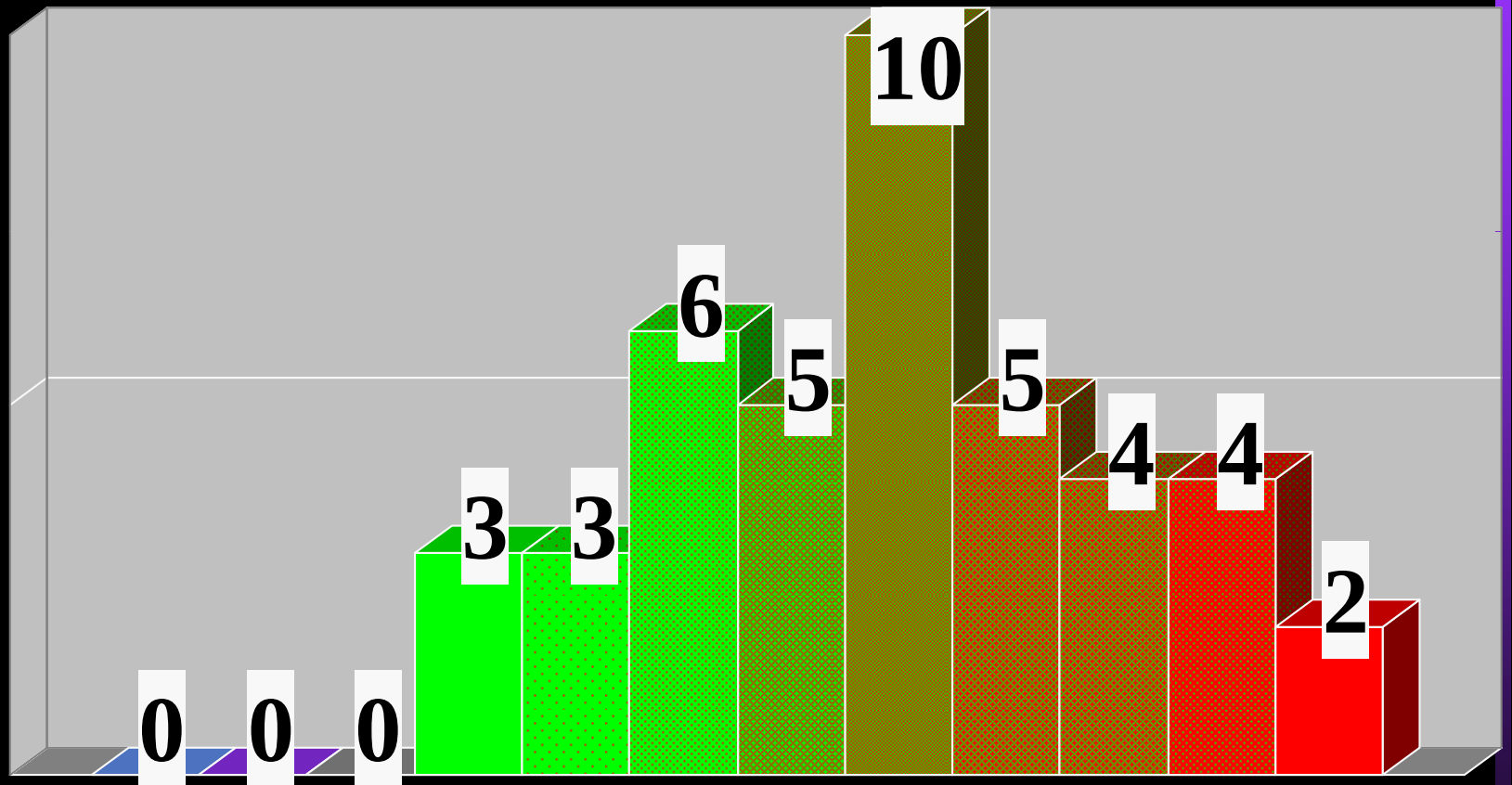


G) Was the statistical analysis appropriate?

0 No
1 Unclear
2 Yes



Methodological scoring of RCTs on dental implants (n=42)



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The quality of RCTs of oral implants is generally poor and needs to be improved

Esposito et al., IJOMI 2001; 16: 783-92

Problems of Cochrane Systematic Reviews

Benefits

- High internal validity
- Minimum bias
- Exhaustive bibliographic search

Problems

- If limited only to RCTs
- If RCT are of poor quality
- If important outcomes are not addressed
- Low external validity – applicability?

The commonly reported outcomes

- Plaque
- Marginal bleeding
- Probing pocket depth
- Probing attachment level
- Radiographic marginal bone level changes

Patient relevance?

Outcomes of higher relevance:

Perceived/self reported:

- Adaptation to prosthesis (satisfaction)
- Appearance
- Function (chewing, speech)
- Dietary significance (intake, selection)
- Health
- Health related Quality of life (psyche, wellbeing, self esteem)
- Social activity

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

Scientific studies with similar aims:

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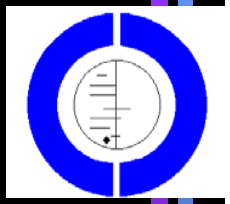


Conclusion:

No evidence that any of the implant systems evaluated was superior to the other.

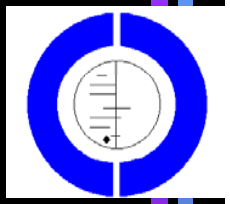
However, these findings are based on a few RCTs all having short follow-up periods and few participants.

Scientific studies with similar aims:

Eckert et al. J Prosthet Dent 1997;77: 271-9.

Esposito M et al. Cochrane Database Syst Rev 2002;(4). (1st vers)

Esposito M et al. Cochrane Database Syst Rev. 2005(1) (3rd and last version)



Conclusion:

There is limited evidence showing that implants with relatively smooth (turned) surfaces are less prone to loose bone due to chronic infection (perimplantitis) than implants with rougher surfaces.

There is no evidence showing that any particular type of dental implant has superior long-term success.

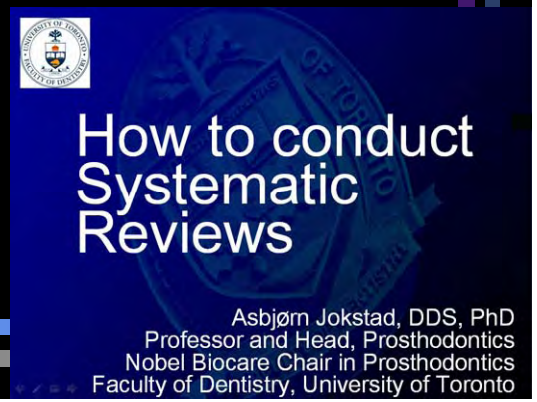
These findings are based on a few RCTs, often at high risk of bias, with few participants and relatively short follow-up periods

Mandate

Mandate: Review

- Comprehensive
- Systematic
- Repeatable

→ typical characteristics of a Systematic Review



Quality of Dental Implants?

1. How many systems are currently marketed globally and what are their characteristics?

   a. Implant material

   b. Implant geometry

   c. Implant surface topography

   d. Clinical documentation

What would you consider to be an extensive clinical documentation of an implant system?

A: >4 prospective and/or retrospective clinical trials?

B: >4 prospective and/or retrospective clinical trials over minimum 5 years ?

C: >8 prospective and/or retrospective clinical trials ?

D: >8 prospective and/or retrospective clinical trials over minimum 5 years ?

E: >10 prospective and/or retrospective clinical trials ?

Levels of Clinical Documentation?

4 Categories: A-B-C-D

A. Implant or implant system with extensive clinical documentation:

more than four prospective and/or retrospective clinical trials

Clinical documentation

A. Implant or implant system with extensive clinical documentation: > 4 prospective and/or retrospective clinical trials

B. Implant or implant system with limited clinical documentation:

< 4 trials, but of good methodological quality:

- randomised controlled trial
- prospective clinical trial

either multicentre or

with study samples consisting of more than 50 patients or 200 dental implants

Clinical documentation

A. Implant or implant system with extensive clinical documentation: >4 clinical trials

B. Implant or implant system with limited clinical documentation, i.e. <4 trials, but of good methodological quality

C. Implant or implant system with limited published clinical documentation and not fulfilling documentation levels A or B

Clinical documentation

A. Implant or implant system with extensive clinical documentation: >4 clinical trials

B. Implant or implant system with limited clinical documentation, i.e. <4 trials, but of good methodological quality

C. Implant or implant system with limited published clinical documentation and not fulfilling documentation levels A or B

D. Implant or implant system with no published clinical documentation.

Quality of Dental Implants?

1. Available systems, characteristics & documentation?

   Material – Geometry - Surface topography

2. How to describe “quality” of dental implants?

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 representative tells you so?
- scientific clinical studies provide an answer?

Regulatory aspects – Implant standards

How many standards exists for dental implants?

A: 1

B: 3

C: 6

D: 9

E: 12

Regulatory aspects – Implant standards

- Europe: EN1642-Dental Implants

Regulatory aspects EN1642-Dental implants

(1) intended performance - (2) design and properties, including add-on components - (3) sterilization and packaging & (4) marking, labeling and information that include:

1. Documentation that a risk assessment has been done (EN14971)
2. Materials:

   -need to comply with property requirements, (EN10451)

   -must be assessed for biocompatibility (EN7405 & EN10993).

   - the prefabricated parts intended to connect a supra-structure need to comply with property requirements (EN14727)
3. The condition dental implants are supplied requires clear description on the package. (EN550, EN552, EN556)
4. The information required needs to comply with details regarding use of symbols and minimum information on labeling and instructions for use.

How many of the approx 80 implant manufacturers in 2003 had tested their products according to existing implant standards?

A: 0

B: 10

C: 20

D: 40

E: 60

Regulatory aspects - production quality control standard

- Europe EN1642-Dental Implants
- ISO9001 / EN46001 (ISO9002 / EN46002)
- FDA GMP (Good Manufacturing Practice)

To avoid:

- inferior materials
- contamination
- poor precision
- Inappropriate packaging / labeling

Regulatory aspects – marketing approval

- Europe EN1642-Dental Implants
- ISO9001 / EN46001 (ISO9002 / EN46002)
- FDA GMP (Good Manufacturing Practice)
- FDA 510(k) (Substantial equivalence to a device marketed before 1976)

FDA 510(k) – Documentation 1/2

- That the submitted product has substantial equivalence to a product that is already on the market with specific information about safety and clinical effectiveness.
- General requirements for indications for use, device description and sterilization information.
- Upon request the manufacturer must also provide data on mechanical, corrosion and biocompatibility testing, as well as characterization of any coatings used.

FDA 510(k) – Documentation 2/2

- Substantial equivalence to a product before 1976
- General requirements for indications for use, device description and sterilization information.
- Data on mechanical, corrosion and biocompatibility testing, as well as characterization of any coatings used.
- Further requests may also include documentation of test reports as well as data from animal and clinical studies.
- Additional requirements need to be fulfilled if the implant coating includes calcium phosphate.

Regulatory aspects – FDA 510(k)

- Since 1976, nearly 98% of new devices entering the market in class II or III have been approved through the 510(k) process.
- In 2002, the FDA reported 41 premarket approvals and 3708 approvals through the 510(k) process.

Regulatory aspects - marketing approval

- Europe EN1642-Dental Implants
- ISO9001 / EN46001 (ISO9002 / EN46002)
- FDA GMP (Good Manufacturing Practice)
- FDA 510(k) (Substantial equivalence)
- EU Directive 93/42/EEC
- 

(accredited by certified body)

Regulatory aspects – other aspects

- Europe EN1642-Dental Implants
- ISO9001 / EN46001 (ISO9002 / EN46002)
- FDA GMP (Good Manufacturing Practice)
- FDA 510(k) (Substantial equivalence)
- EU Directive 93/42/EEC
- 

(accredited by certified body)
- ISO1942-5 (TC106 SC3)
- ISO10451 (TC106 SC8)

Quality of Dental Implants?

1. Available systems, characteristics & documentation?

   Material – Geometry - Surface topography

2. Quality of implants & -systems?

3. Claims of superiority of implant design and validation according to levels of scientific evidence and required study designs

Materials and methods - process

M&M – Promotional material

In all types of information sources:

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

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

1. *Adherence to quality control system*
2. *Manufacturers' claims of superiority*

Materials and methods

Promotional material

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

PICO:

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

Implant Direct's Replant™ VS Nobel's *Replace Select

SURGICAL AND PROSTHETIC COMPATIBILITY

RePlant Implant is inserted with Nobel *Replace Surgical Instruments

RePlant Platform is Compatible with Nobel *Replace Abutments

PRICE COMPARISON - SAVE 60% FOR STRONGER, BETTER DESIGN

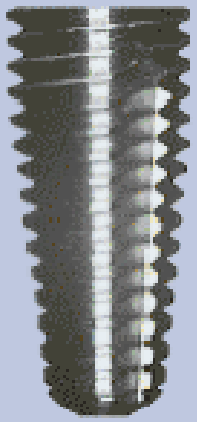
4mm Deep Tri-lobe Internal Connection

Implant Direct RePlant Implant
US PRICES Incl. COVER SCREW
3.5, 4.5, 5.0 & 6.0mmD = $150
Straight Snap-On Abutment = $75

Nobel *Replace Select Implant
US PRICES Incl. COVER SCREW
3.5, 5.0 & 6.0mmD = $384; 4.3mmD = $365
Straight Snap-On Abutment = $182

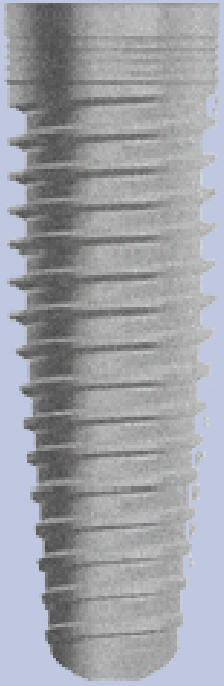
1.5mm Deep Tri-lobe Internal Connection

Picture of RePlant Tapered Body



RePlant Design Advantages

- Quadruple Lead Micro-Threads For Reduced Crestal Bone Stress
- Double Lead Standard "V" Threads For 2X Faster Insertion
- Long Self-Tapping Groove & Apical Threads For Better Initial Stability



Picture of RePlace Tapered Body

TITANIUM ALLOY FOR STRENGTH (SBM SURFACE)

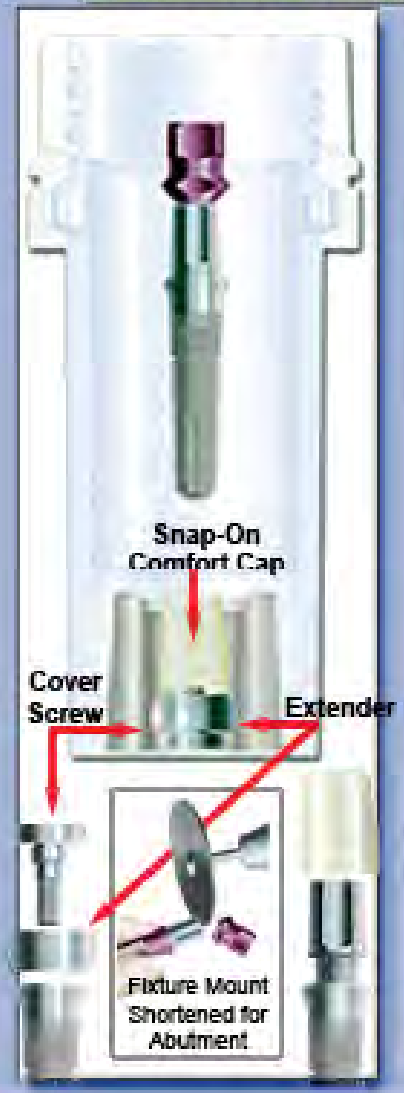
CP TITANIUM WITH *TIUNITE SURFACE (Alloy on HA)

*RePlace Select and TiUnite are Trademarks of Nobel Biocare Inc.

www.implantdirect.com

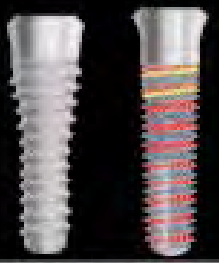
ScrewPlus Implant vs Straumann's ITI Tapered Implant

ScrewPlus Implant Packaging Includes
Fixture Mount (Transfer and Final Abutment)
Cover Screw, 2mm Extender and Snap-on Comfort Cap



Straumann ITI Tapered Implant
Includes Cover Screw Only

COMPARE US PRICES



Compare US List Price	ITI Tapered Implant	Screw Plus Implant
Implant	$305.00	$150
Cover Screw	$34.50	Included
Healing Cap	$48.00	2mm Included
Straight Abutment	$129.00	Included
Protective Cap	$7.50	Included
Transfer	$7.50	Included
TOTAL US List Price	$521	$150
SAVINGS	3.5X	71%

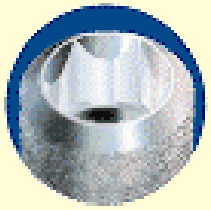
Compare ScrewPlant to 3i's™ Certain* Implant

ScrewPlant Implant

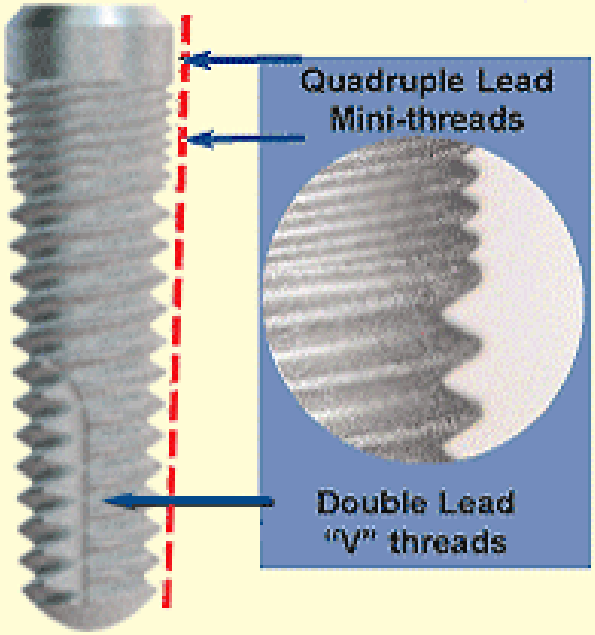
1. SBM Blasted Surface 20u pits
2. Mini-Threads & Double-lead Threads
3. Body Taper starts at Top
4. Internal Hex 2mm Deap x 2.5mmD
5. Angled Abutments Indexed to Hex

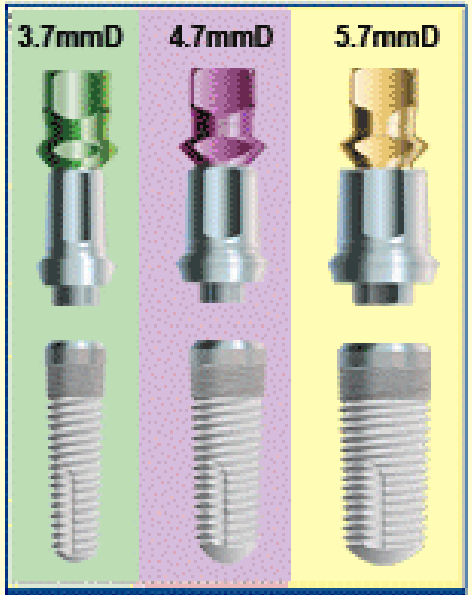
US List Price: $150 Complete

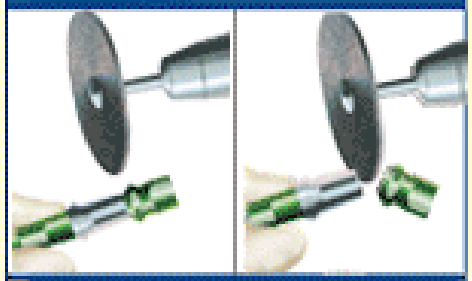
Includes Healing Collar, Straight Abutment, Snap-on Cap and Transfer

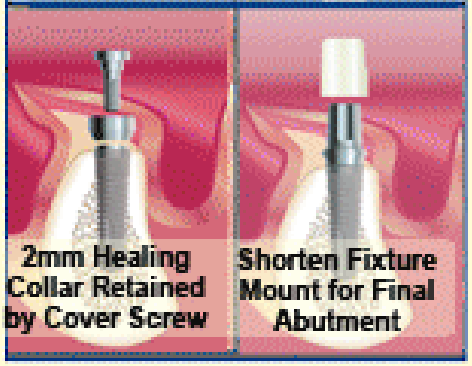


Tapered Evenly Down From To - Expansion in Soft Bone increases initial stability







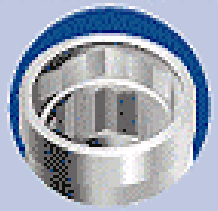


3i Certain™ Implant

1. Acid Etched Osseotite 1-2u Pits
2. Minimal Thread Surface
3. Body Tapers from mid-point.
4. Internal Hexes 3mmD & 2.5mmD
5. No Indexing - need Encode™ Collars

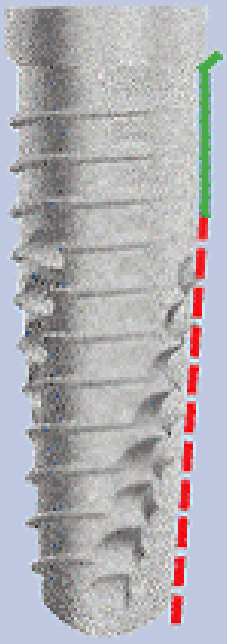
US List Price: $536 Complete

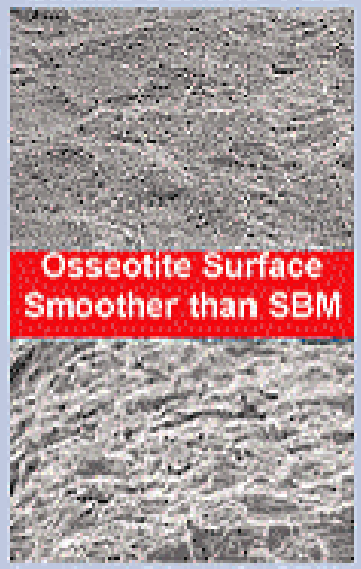
Implant ($319) +Healing Collar ($45) +Abutment ($147) +Cap ($13) +Transfer (12)



Large Hex requires Wider Neck. Taper is only in in apical half of body

3i's Osseotite Acid Etched Surface 1-2u





Implant Direct's SBM Blasted Surface 20u

www.implantdirect.com

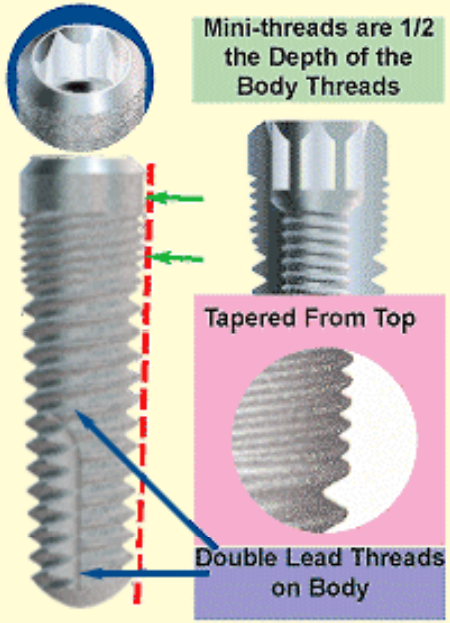
Compare ScrewPlant to Astra's Micro-Thread Implant

ScrewPlant Implant

1. SBM Blasted Surface to Top
2. Mini-Threads + Double-Lead Threads
3. Body Tapered for Anatomical Requirements and Initial Stability
4. Fixture-Mount Engages Hex - No Counter-Torque needed to remove
5. *Fixture-Mount is Transfer and Abutment

US List Price: $150 Complete

Healing Collar(2mm), Abutment/Cap, Transfer and Cover Screw Included



Mini-threads are 1/2 the Depth of the Body Threads

Tapered From Top

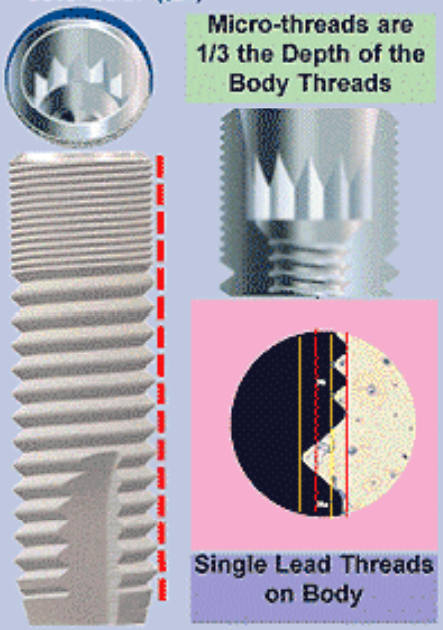
Double Lead Threads on Body

Astra Implant

1. TiO_2 Blasted Surface to Top
2. Micro-threads + Single-lead Threads
3. Straight Body. Optional Implant only provides taper in Micro-Thread area.
4. Fixture-Mount fictional engagement Counter-torque needed to remove.
5. Fixture Mount serves single purpose

US List Price $537.50 Complete:

Implant($295) + Healing Collar ($50) +Abutment /Cap ($140.75) + Transfer ($24.75) + Cover Screw ($27)



Micro-threads are 1/3 the Depth of the Body Threads

Single Lead Threads on Body

's *Screw-Vent®

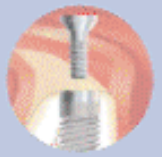
Screw-Vent Implant

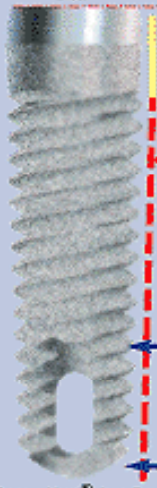
1. Machined Surface 1.5mm from Top
2. Triple Lead Threads overall
3. Body Taper starts 2.5mm from Top
4. Short Cutting Groove & Vent
5. Fixture-Mount is Transfer & can be Shorten for *Temporary Abutment*

US List Price: $512 Complete

Implant ($325) + Healing Collar($42) +Abutment with machined margin ($145)

Internal Bevel 1.4mm Internal Hex





First 3mm of Neck
1.5mm Machined
1.5mm MTX Blast

Taper Starts below 2.5mm Straight Neck

Triple Lead "V" Threads

Short Cutting Groove. Apical Vent not needed in Tapered Implant

Materials and methods

Promotional material

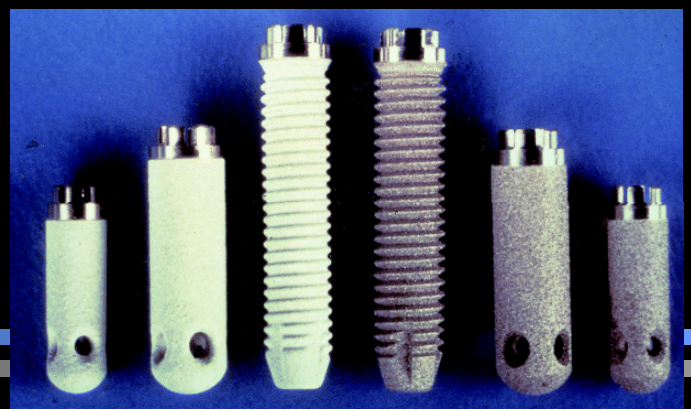
Brochures, trade exhibitions, WWW, leaflets, presentations, etc.

PICO:

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

Differences in implant material:

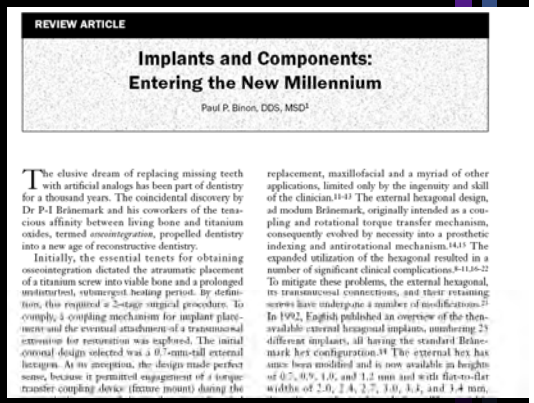
- C.p.1 Titanium (e.g. Nobel Biopharma)
- C.p.2 Titanium
- C.p.3 Titanium (e.g. Straumann)
- C.p.4 Titanium (e.g. AstraTech)
- Titanium-alloys (e.g. C.p.5: Ti-6Al-4V)
- Hydroxyapatite
- ....




How to characterize
complex body geometries?

Differences in implant body geometry:

- Major morphological form
- Flange design
- Main body w/wo threads
- Apex form, grooves & vents
- Interface geometry
- Surface topography



REVIEW ARTICLE

Implants and Components: Entering the New Millennium

Paul P. Binon, DDS, MSD[1]

The elusive dream of replacing missing teeth with artificial analogs has been part of dentistry for a thousand years. The coincidental discovery by Dr P-I Brånemark and his coworkers of the tenacious affinity between living bone and titanium oxides, termed *osseointegration*, propelled dentistry into a new age of reconstructive dentistry.

Initially, the essential tenets for obtaining osseointegration dictated the atraumatic placement of a titanium screw into viable bone and a prolonged undisturbed, submerged healing period. By definition, this required a 2-stage surgical procedure. To comply, a coupling mechanism for implant placement and the eventual attachment of a transmucosal extension for restoration was explored. The initial coronal design selected was a 0.7-mm-tall external hexagon. At its inception, the design made perfect sense, because it permitted engagement of a torque transfer coupling device (fixture mount) during the replacement, maxillofacial and a myriad of other applications, limited only by the ingenuity and skill of the clinician.[11-13] The external hexagonal design, ad modum Brånemark, originally intended as a coupling and rotational torque transfer mechanism, consequently evolved by necessity into a prosthetic indexing and antirotational mechanism.[14,15] The expanded utilization of the hexagonal resulted in a number of significant clinical complications.[8-11,16-22] To mitigate these problems, the external hexagonal, its transmucosal connections, and their retaining screws have undergone a number of modifications.[23]

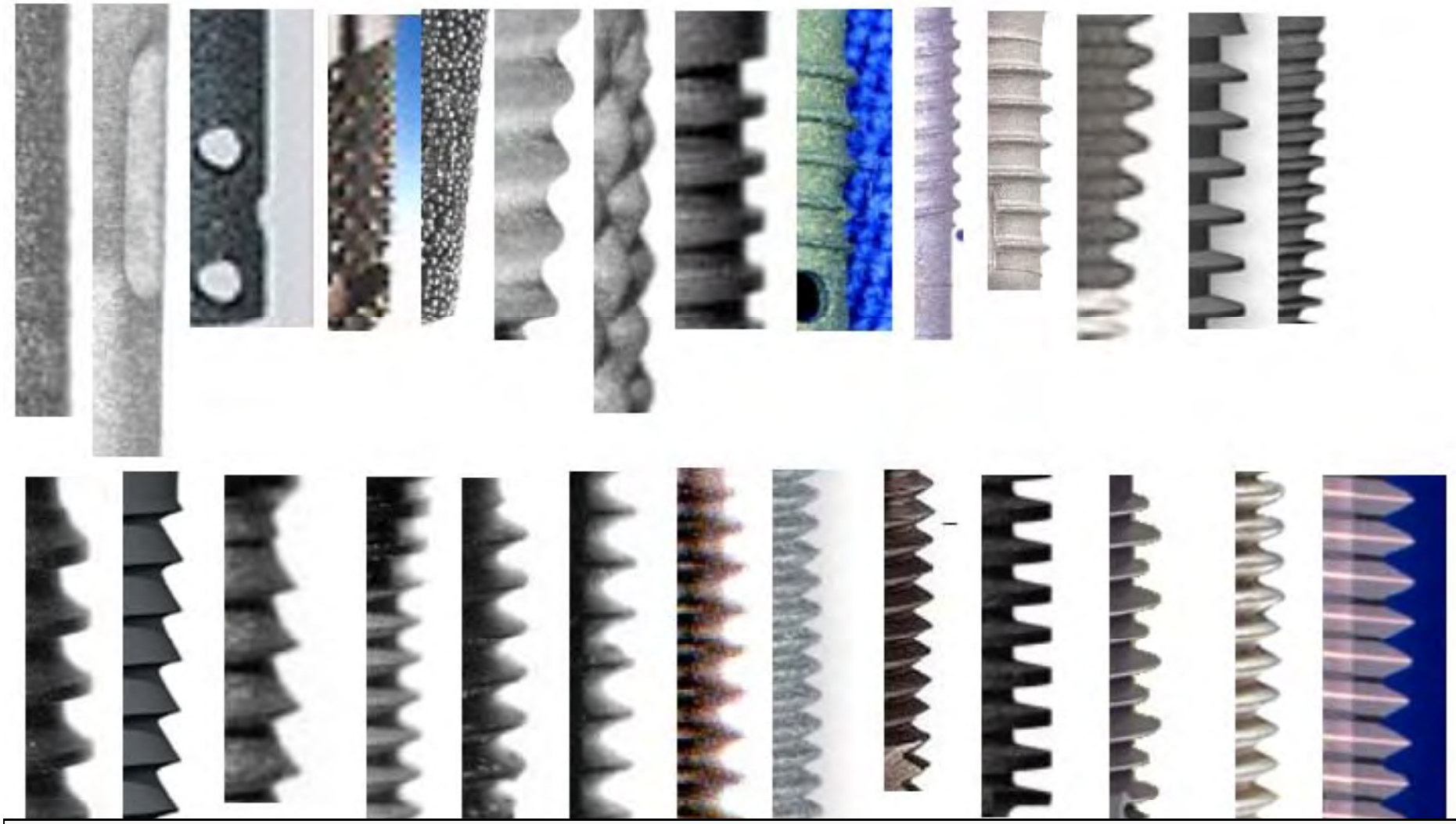
In 1992, English published an overview of the then-available external hexagonal implants, numbering 23 different implants, all having the standard Brånemark hex configuration.[24] The external hex has since been modified and is now available in heights of 0.7, 0.9, 1.0, and 1.2 mm and with flat-to-flat widths of 2.0, 2.4, 2.7, 3.0, 3.4, and 3.4 mm.

Binon, IJOMI, 2000, 15(1): 76-95

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



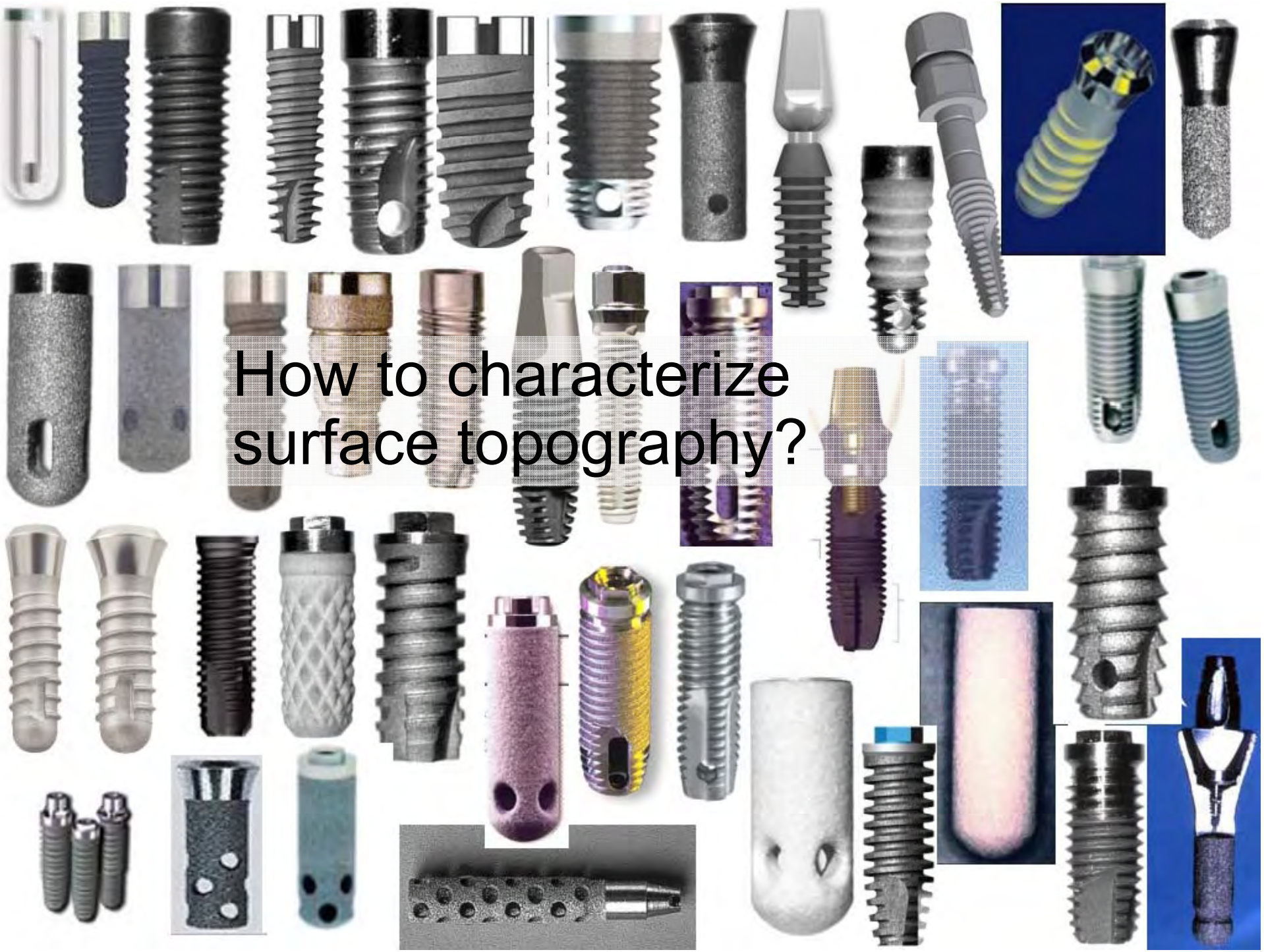
- Threads vs. non-threads
- Shape: V- vs. square- vs. reverse buttress- vs. combinations
- Number and size of “lead threads”
- Number and location of grooves, groove forms and groove sizes
- Surface micro-topography
- Thread angle

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

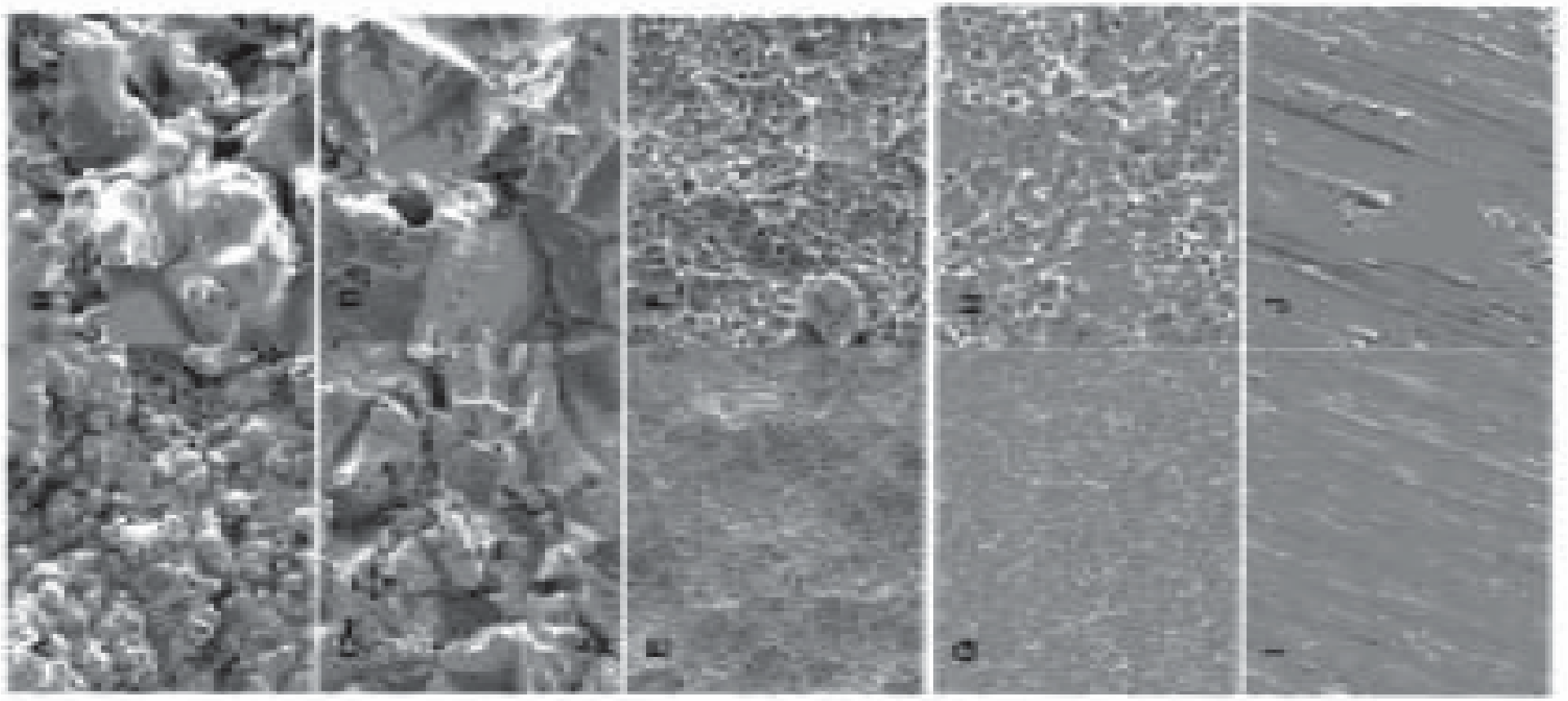
Interface geometry

- 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 ….


How to characterize
surface topography?

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)

High (top) and low (bottom) magnification of cpTi surfaces as used for surface characterization.



Plasma–sprayed (TPS);

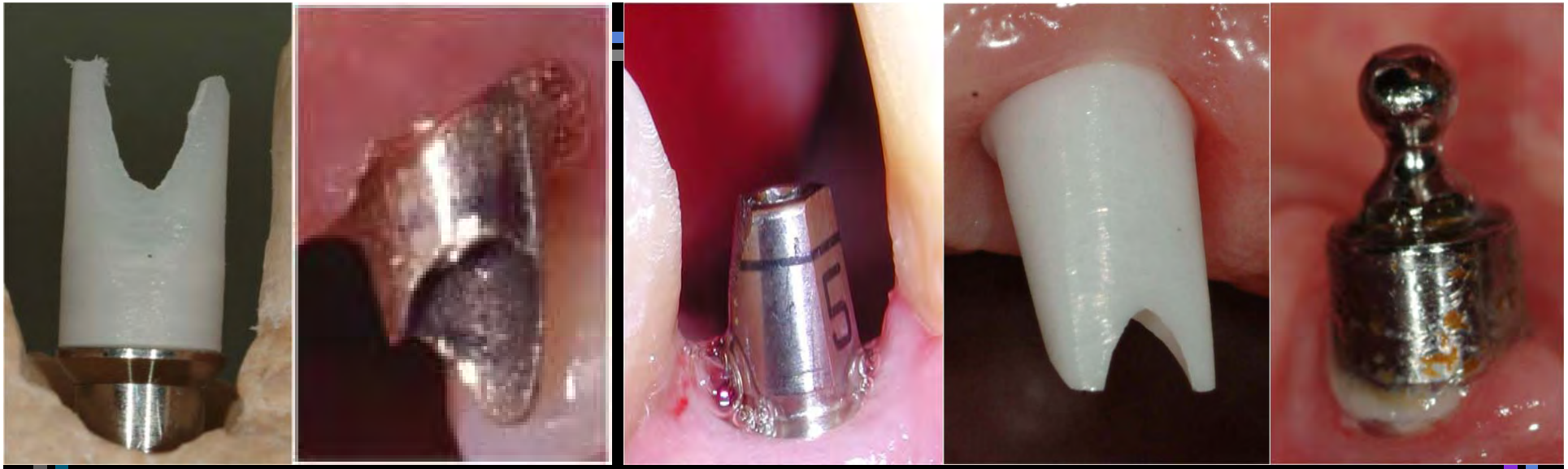
Grit-blasted

Grit-blasted and dual acid-etched

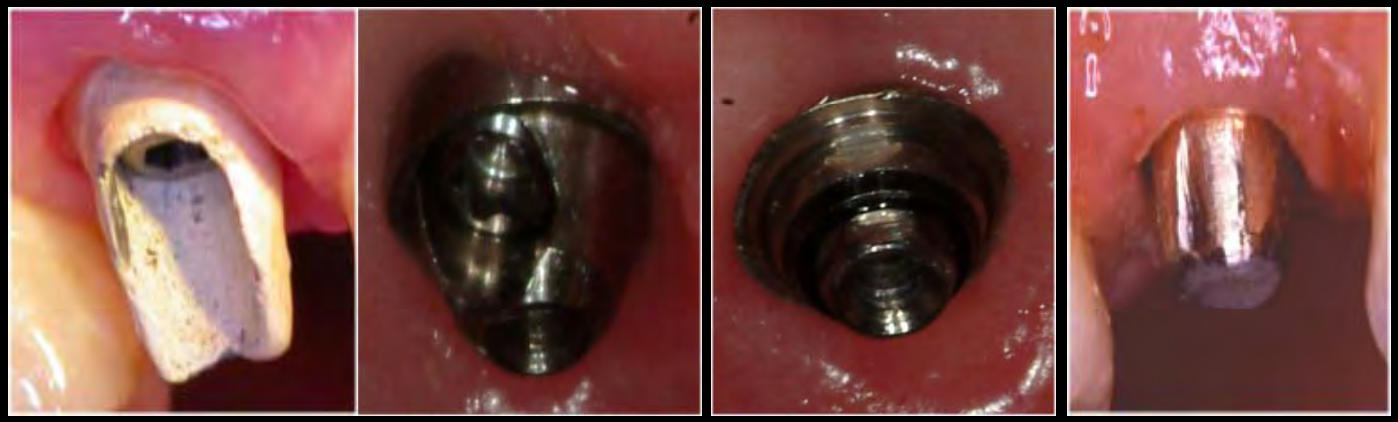
Dual acid-etched

Machined (turned)

Davies, 2003



How to characterize implant abutments?



Differences between implant abuments

- Geometry
- Material
  - Metal, ceramic, other
- Surface topography
  - roughness

Materials and methods

Promotional material

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

PICO:

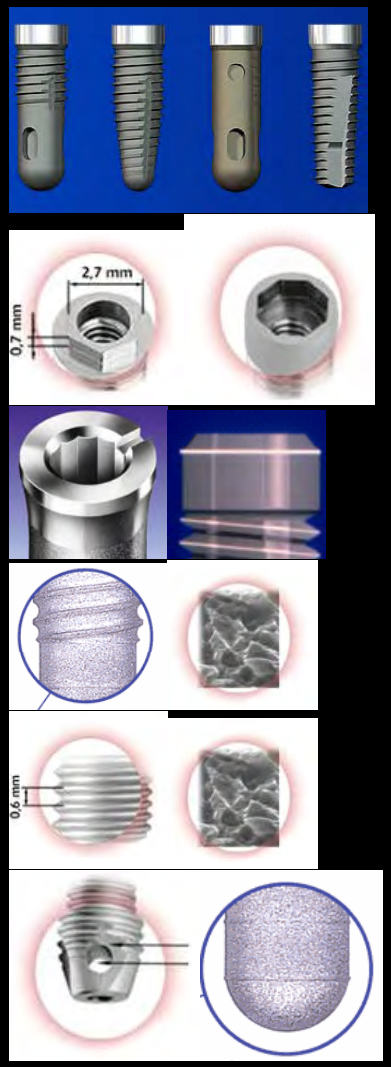
Problem:	Intervention	Comparison	Outcomes
Claims of superiority	Implant w/ characteristic (material, geometry, surface topography)	Implant without characteristic	Clinical relevant & Clinical significant

Categories of clinical outcomes

1. Ease of placement
2. Osseointegration predictability
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

Clinical outcomes and implant characteristics

1. Ease of placement
2. Osseointegration predictability
3. Esthetics
4. Peri-implant mucositis
5. Marginal bone loss
6. Mechanical problems implant/abutment/ superstructure
7. Mechanical failing



+ material & dimensions

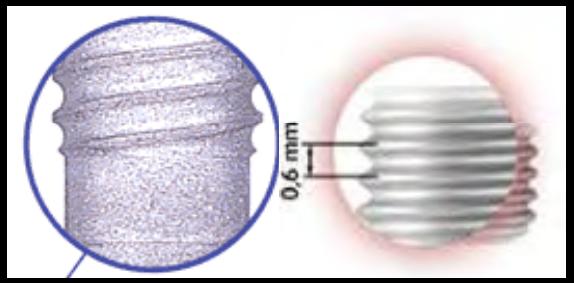
+Abutment - material and geometry

Design characteristics of the dental implant that may be associated with clinical success

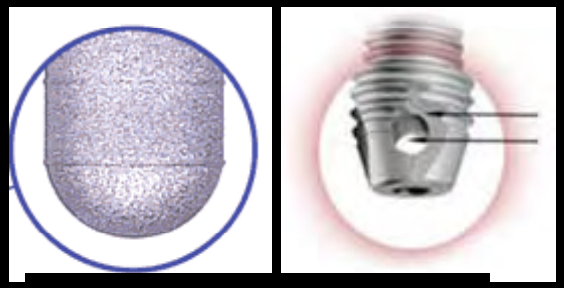
Clinical outcome

Ease of placement

General geometry



Coronal / Midbody form



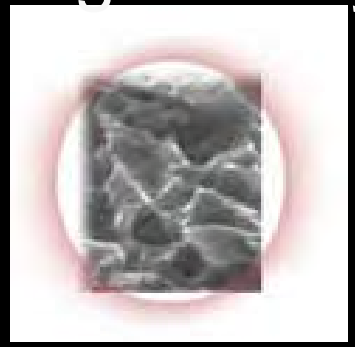
Apical form

Design characteristics of the dental implant that may be associated with clinical success

Clinical outcome

Osseo-integration

General geometry



Surface topography

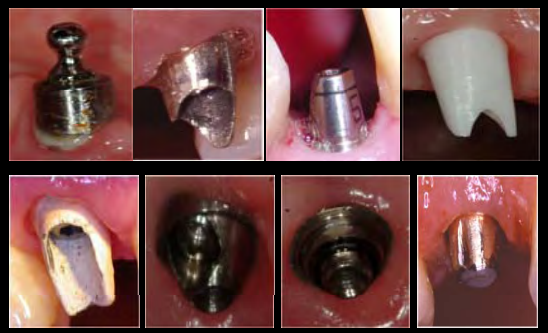
Implant material

Design characteristics of the dental implant that may be associated with clinical success

Clinical outcome

Esthetics

Implant and abutment interface geometry



Abutment material, geometry & surface

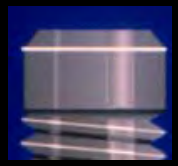
Design characteristics of the dental implant that may be associated with clinical success

Clinical outcome

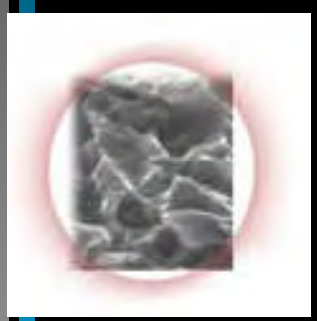
Peri-implant mucositis

General geometry

Implant:abutment interf



Implant flange



Surface topography

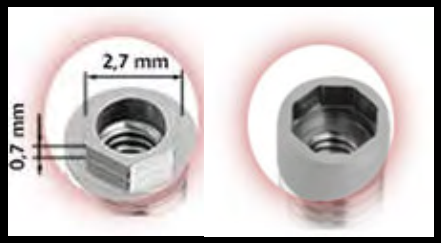
Implant material

Abutment material, geometry & surface

Design characteristics of the dental implant that may be associated with clinical success

Clinical outcome

Mechanical problems of the implant/ abutment/ superstructure connections



Implant:abutment interface

(Joint geometry strength, precision fit of components, torque reliability, i.e. clamping force)

Implant material

Abutment material & geometry

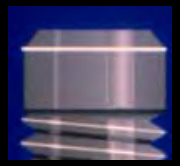
Design characteristics of the dental implant that may be associated with clinical success

Clinical outcome

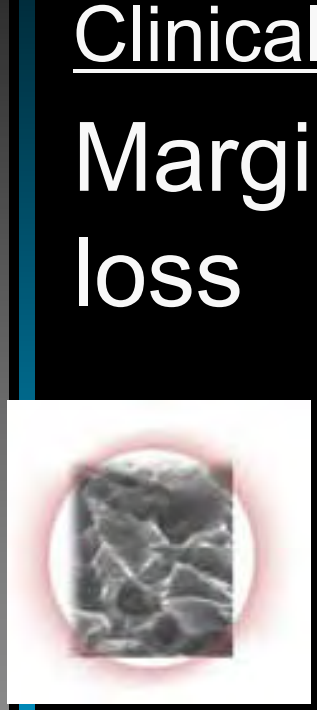
Marginal bone loss

General geometry

Implant:abutment interf



Implant flange



Surface topography

Implant material

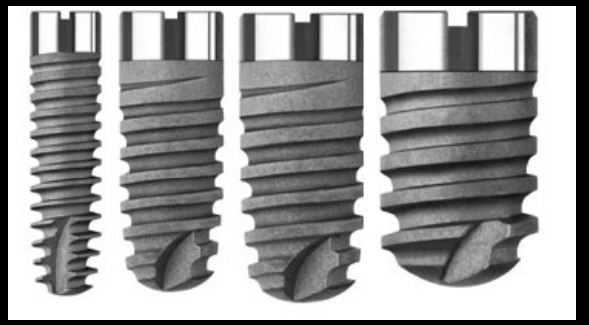
Abutment material, geometry & surface

Design characteristics of the dental implant that may be associated with clinical success

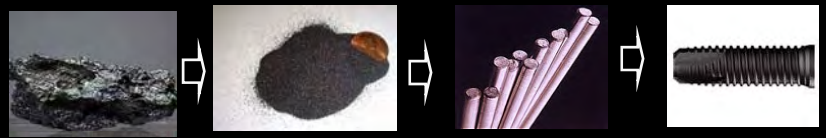
Clinical outcome

Mechanical failing of the dental implant

General geometry



Implant dimensions



Implant material

Strength of Evidence for a causal relationship?

Methodological designs of clinical implant trials and their power to answer a research question

Asbjørn Jokstad
University of Toronto

Scientific Evidence of Causality

- *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.).*

Where to find best evidence on implant therapy in the scientific literature?

Searching for evidence on dental implant therapy

Asbjørn Jokstad
University of Toronto

Results

N=1270

1. Dental implant systems currently marketed globally, their characteristics and documentation

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

A. Implant or implant system with extensive clinical documentation: >4 clinical trials	10
B. Implant or implant system with limited clinical documentation, i.e. <4 trials, but of good methodological quality	11
C. Implant or implant system with limited published clinical documentation	29
D. Implant or implant system with no published clinical documentation.	28

2. Quality of dental implants & system components?

Table 3 Clinical studies where one or more implant characteristic has been associated with the clinical performance, identified as Geometry -, Material -, Surface topography or combinations of these (Complex). Sorted by study design, characteristic and first author name.

Study design*	Reported or appraised influence of implant characteristic on clinical performance	Sample (n)	Per. (yrs)	Authors
RCT	Complex: Brånemark System® vs IMZ® vs ITI®	(30x3)x2	1	Batenburg *et al.* 1998 (The Netherlands)[24]
RCT	Complex: Astra Tech vs Brånemark System®	184+187	3 1	Engquist *et al.* 2002[25] Åstrand *et al.* 1999 (Sweden)[26]
RCT	Complex: Astra Tech vs ITI®	56+46	1	Kemppainen *et al.* 1997 (Finland)[27]
RCT	Complex: Brånemark System® vs IMZ®	(32+29)x2	5	Meijer *et al.* 2000 (The Netherlands)[28]
RCT	Complex: Brånemark System® vs ITI®	102+106	3	Moberg *et al.* 2001 (Sweden)[29]
RCT	Complex: Southern vs Sterioss	48x224x2	2 1	Tawse-Smith *et al.* 2002[16] Tawse-Smith *et al.* 2001 (New Zealand)[30]
RCT	Geometry: IMZ® 1-stage vs IMZ® 2-stage vs ITI®, TPS coatings	(20x3)x2	2	Heydenrijk *et al.* 2003[31]
	IMZ® vs ITI®, TPS coatings	(20x2)x2	1	Heydenrijk *et al.* 2002[32] Meijer *et al.* 2003 (The Netherlands)[33]
RCT	Material: Sterngold-Implamed®, plasma-spray Ti vs HA coated	176x2	5 <1	Jones *et al.* 1999[34] Jones *et al.* 1997 (USA)[35]
RCT	Material: IMZ®, Ti plasma-spray vs HA coated	147+145	3-7	Mau *et al.* 2002 (Germany)[36]
RCT	Surface: Brånemark System® Standard vs TiUnite	55+66	1	Rocci et al. 2003 (Italy)[37]

Study design*	Reported or appraised influence of implant characteristic on clinical performance	Sample (n)	Per. (yrs)	Authors
Split-RCT	Complex: Brånemark System® vs ITI®	77+73	1	Åstrand *et al.* 2002 (Sweden)[38]
Split-RCT	Complex: Steri-Oss TPS vs HA screw vs HA cylinder (brand not described)	634	3	Geurs *et al.* 2002 (USA)[39]
Split-RCT	Complex: Brånemark System®, vs HA screw vs HA cylinder (brand not described)	615	5	Jeffcoat *et al.* 2003 (USA)[40]
Split-RCT	Complex: Spectra system, HA groove vs HA screw vs HA cylinder vs Ti screw vs Ti-alloy basket vs Ti-alloy screw	2641 2633 1565	<1 <1 <1	Orenstein *et al.* 1998[41] Truhlar *et al.* 1997[42] Ochi *et al.* 1994 (USA)[43]
Split-RCT	Complex: Astra Tech vs Brånemark System®	45+50	2	van Steenberghe *et al.* 2000 (Belgium)[44]
Split-RCT	Geometry: Brånemark System®, standard vs Mk IV screws	44x2	1	Friberg *et al.* 2003 (Sweden)[45]
Split-RCT	Surface: Astra Tech, turned Ti vs TiO_2 –blasted	64+64	5 2	Gotfredsen & Karlsson 2001[46] Karlsson *et al.* 1998 (Scandinavia)[47]
Split-RCT	Surface: 3i, Dual-etch vs turned Ti	247+185	2-5	Khang *et al.* 2001 (USA)[48]
Split-RCT	Surface: ITI®, SLA vs TPS	68x2	1	Roccuzzo *et al.* 2001 (Italy)[14]
CCT	Complex: Brånemark System® vs ITI®	160+78	1–3	Becker *et al.* 2000 (USA)[49]
CCT	Complex: Brånemark Conical® vs FriaLoc vs Ha-Ti® vs ITI®	40+40+164+84	3–8	Chiapasco & Gatti 2003 (Italy)[50]
CCT	Complex: Brånemark System® Standard, MKII & MKIII vs ITI® SLA	78+80	2–5.5	Pinholt 2003 (Denmark)[51]
Split-CCT	Complex: 3i, 2 geometries, turned Ti, HA & TPS	15x3	3	Røynesdal *et al.* 1998 (Norway)[52]
Split-CCT	Complex: 3i, 2 geometries, turned Ti, HA & TPS	15x3	3	Røynesdal *et al.* 1999 (Norway)[53]
Split-CCT	Geometry: Brånemark System®, standard vs self-tapping screws	288+275 288+275 88+91	5 3 1	Friberg *et al.* 1997[54] Olsson *et al.* 1995[55] Friberg *et al.* 1992 (Sweden)[56]

Table 4 Clinical studies where one or more implant abutment characteristic has been associated with the clinical performance, identified as Geometry -, Material -, Surface topography or combinations of these (Complex). Sorted by study design, characteristic and first author name.

Study design*	Reported or appraised influence of implant characteristic on clinical performance	Sample (n)	Period (yrs)	Authors
RCT	Geometry: Brånemark system® Standard vs transmucosal abutment	5x4x2	2	Gatti & Chiapasco 2002 (Italy)[85]
Split-RCT	Material: Brånemark system® Ti vs ceramic abutment	34x2 +10x2	1& 3	Andersson *et al.* 2001 (Sweden)[86]
Split-RCT	Material: IMZ® Ti vs ceramic abutment	14x2	12 wks	Barclay *et al.* 1996 (UK)[87]
Split-RCT	Material: Brånemark system® Ti vs ceramic abutment	6x2	1	Bollen *et al.* 1996 (Belgium)[88]
Split-RCT	Surface: Brånemark system® Ti abutments with 4 different surface roughness	6x4	3mths	Quirynen *et al.* 1996 (Belgium)[89]
CCT	Geometry: Omniloc® 2 abutments	429	5–7	McGlumphy *et al.* 2003 (USA)[90]
CS	Complex: IMZ® & IME/IMC vs ITI® & Octa abutment	138+50	0.5-8	Behr *et al.* 1998 (Germany)[91]
CS	Geometry: Spline® vs Threadlock® abutments	44+52	3	Bambini *et al.* 2001 (Italy)[92]
CS	Geometry: Brånemark system® 3 abutment screws	1170	1–10	Eckert & Wollan 1998 (USA)[93]
CS	Geometry: Brånemark system® 2 abutments	259	1–9	Scholander 1999 (Sweden)[94]

*RCT: Randomised controlled trial, Split-RCT: Split mouth randomised controlled trial CCT: Controlled clinical trial, CS: Case Series

Study design* & focus & number of studies	Study reference	Clinical outcome: Ease of placement	Osseointegration (early & late)	Esthetics	Peri-implant mucositis	Marginal bone loss	Mechanical problems of interface	Mechanical failing of implant
A1								
Geometry:2	[31-33][85]	–	[31–33]	–	[31-33][85]	[31-33][85]	[31]	–
Material:2	[34,35][36]	–	[34,35][36]	–	–	–	–	[36]
Surface:1	[37]	–	[37]	–	–	[37]	–	–
Complex:6	[24][25,26][27] [28][29][16,30]	[26][29]	[24][25,26][27] [28] [29][16,30]	[27]	[24][25,26][27] [28][29][16,30]	[24][25,26][27] [28][29][16,30]	[25,26] [28][29]	– –
A2								
Geometry:1	[45]	[45]	[45]	–	–	–	–	–
Material:3	[86][87][88]	–	–	[86]	[86][87][88]	[86]	[86]	–
Surface:4	[14][46,47][48][89]	–	[14][46,47][48]	–	[14][47][89]	[14][46]	–	[46]
Complex:5	[38][39][40] [41–43][44]	[44]	[38][41-43][44]	–	[39][40][44]	[38][40][44]	–	–
B								
Geometry:2	[54-56][90]	[54-56]	–	–	–	[54-56]	[90]	–
Material:0	–	–	–	–	–	–	–	–
Surface:0	–	–	–	–	–	–	–	–
Complex:5	[49][50][51][52][53]	–	[49][50][51]	–	–	[49][52][53]	–	–
C								
Geometry:17	[19][68][69][70][71] [72][73][74][75] [76,77][78][79][80] [81][92][93][94]	–	[19][74][75] [76,77][78][80] [81]	–	–	[70][73]	[68][92] [93][94]	[76,77]
Material:2	[82][83]	–	[82][83]	–	–	–	–	–
Surface:1	[84]	–	[84]	–	–	–	–	–
Complex:11	[57][58][59,60] [18,61][62][63][64] [65][66][67][91]	–	[57][58][59,60] [18,61][64][65] [66][67]	–	[18,61][62]	–	[63][91]	–

126 clinical studies relate 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	2	0	2	4
	78	14	34	126

Claims of improved clinical outcomes: Ease of placement

	RCTs	CCTs	Other	
1. Ease of placement	4	3	0	7

7 clinical studies related a specific implant characteristic to: Ease of placement

	RCTs	CCTs	Other	
Implant geometry	1	3		4
Implant material				0
Implant surface				0
Complex study design	3			3
	4	3	0	7

7 clinical studies related a specific implant characteristic to: Ease of placement

	RCTs	CCTs	Other	
Implant geometry	1	3		4
Implant material				0
Implant surface				0
Complex study design	3			3
	4	3	0	7

Differences in ease of placement, as a function of the implant morphology has not been systematically evaluated in clinical trials.

Two reported surrogate outcomes are operation time and surgeons' preference.

7 clinical studies related a specific implant characteristic to: Ease of placement

	RCTs	CCTs	Other	
Implant geometry	1	3		4
Implant material				0
Implant surface				0
Complex study design	3			3
	4	3	0	7

Possible slight effect of implant geometry on primary stability, albeit operator bias cannot be avoided.

Changes in implant geometry may improve the ease of placement as reported by the surgeon. However, the study design does not control for possible operator bias regarding implant preference.

7 clinical studies related a specific implant characteristic to: Ease of placement

	RCTs	CCTs	Other	
Implant geometry	1	3		4
Implant material				0
Implant surface				0
Complex study design	3			3
	4	3	0	7

Slight evidence that implant brand can be associated with time needed for surgery. However, as none of the studies were in any way blinded, investigator preferences may have influenced both the actual trial procedures as well as the trial reporting.

Comment 1/2

- ‘Ease of placement’ is a rather vague description for a characteristic of a dental implant.
- It comprises the obvious benefit of a tapered form versus a straight implant in situations with limited space for a single tooth replacement.
- The issue becomes more complex when addressing self-tapping versus nonself-tapping implants, and claims of benefit of specific implant apex morphologies related to primary implant stability.

Comment

- A lack of strict adherence to adequate bone site preparation may be more detrimental for the initial stability than specific morphological characteristics of the implants.
- Given the required surgical proficiency needed to prepare bone for implants, it is improbable that small differences in implant geometry would have any effect on the surgeons' impression of 'ease of placement'.
- 'Ease of placement' is not necessarily related to 'time'. Any surgical procedure that increases the risk for overheating of bone is definitely not recommended

Osseointegration

Claims of improved clinical outcomes: Osseointegration

	RCTs	CCTs	Other	
1. Ease of placement	4	3	0	7
2. Osseointegration	25	3	21	49

49 clinical studies related a specific implant characteristic to: Osseointegration

	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

49 clinical studies related a specific implant characteristic to: Osseointegration

	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

Very few comparative studies exist that report the predictability or rate of osseointegration as a function of isolated geometry influence (i.e. material and surface treatment being identical), due to material influence (i.e. surface treatment and geometry being identical), or due to surface treatment influence (i.e. material and geometry being identical). The few studies that have been carried out are of relatively short observation periods.

49 clinical studies related a specific implant characteristic to: Osseointegration

	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

Geometry influence was addressed in one RCT and one split-mouth RCT, but found no influence on performance.

Material influence has been assessed in two RCTs, which indicate either minor differences or present ambiguous data.

Surface topography influence has been addressed in one RCT and three split-mouth RCTs, which suggest slightly better results with some forms of surface treated implants compared to turned ones.

49 clinical studies related a specific implant characteristic to: Osseointegration

	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

These studies fail to demonstrate clear differences between different implant brands regarding osseointegration.

This was also corroborated in a three CCT trials. However, as none of these latter studies were blinded, investigator preferences may have influenced both the actual trial process as well as the trial reporting.

49 clinical studies related a specific implant characteristic to: Osseointegration

	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

A heterogeneous group of clinical studies employing different strategies to clarify a relationship between implant morphology and osseointegration failure present contrasting conclusions, as expected in view of the increased probability of spurious statistical associations found in clinical studies with weak methodological designs. A positive element of these studies is the often large patient samples and/or long observation periods, but the risk of various forms of bias introduced in the results should be recognized.

Comment

- Although there may be treatment situations where rapid osseointegration is desirable, the merits of a rapid osseointegration must not overshadow the long-term clinical outcomes.
- Few studies present data from long time follow-up, i.e. more than 5 years
- The few studies can at best be characterized as prospective case series of single implants,
- Occasionally it is just too apparent that the study is published merely as a covert promotion of a specific implant brand.
- Hardly any comparable data of different implants exists have been followed for 5 years, and none beyond 5 years

Comment – short & wide implants 1/2

- The belief that “short implants” are worse of than longer can be challenged.
- May be due to reports having severe statistical flaws or weak methodologically
- No prospective studies published
- It cannot be ruled out that the reported association between implant lengths and clinical failure is a reflection of anatomical limitations in actual treatment situations. I.E., implant length is a surrogate variable for what actually represents differences in case and site selections in clinical trials.

Comment – short & wide implants 2/2

- Beware that the term ‘short’, means in some papers 6–7mm length, while in others anything less than, for example,14mm
- Same discussion about study methodology applies to wide versus regular implants

Esthetics

Claims of improved clinical outcomes: Esthetics

	RCTs	CCTs	Other	
1. Ease of placement	4	3	0	7
2. Osseointegration	25	3	21	49
3. Esthetics	1	1	0	2

2 clinical studies related a specific implant characteristic to: Esthetics

	RCTs	CCTs	Other	
Implant geometry				0
Implant material	1			1
Implant surface				0
Complex study design	1			1
	1	1	0	2

2 clinical studies related a specific implant characteristic to: Esthetics

	RCTs	CCTs	Other	
Implant geometry				0
Implant material	1			1
Implant surface				0
Complex study design	1			1
	2	0	0	2

Only one RCT and one split-mouth RCT have included this outcome as part of the reporting. Both studies concluded that the esthetic outcome is associated neither with implant system nor abutment material.

Peri-implant mucositis

Claims of improved clinical outcomes: Peri-implant mucositis

	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

24 clinical studies related a specific implant characteristic to: Peri-implant mucositis

	RCTs	CCTs	Other	
Implant geometry	4			4
Implant material	3			3
Implant surface	3			3
Complex study design	11		3	14
	21	0	3	24

24 clinical studies related a specific implant characteristic to: Peri-implant mucositis

	RCTs	CCTs	Other	
Implant geometry	4			4
Implant material	3			3
Implant surface	3			3
Complex study design	11		3	14
	21	0	3	24

The influence of implant/ abutment geometry on peri-implant mucositis could not be established in two RCTs.

The influence of implant/ abutment material is inconclusive based on three small split-mouth RCTs.

The influence of implant/ abutment surface topography, is inconclusive evaluated in three split-mouth RCTs.

24 clinical studies related a specific implant characteristic to: Peri-implant mucositis

	RCTs	CCTs	Other	
Implant geometry	4			4
Implant material	3			3
Implant surface	3			3
Complex study design	11		3	14
	21	0	3	24

Implants with different geometry, material and surfaces were evaluated in six RCTs and 3 split-mouth RCTs. Minor differences regarding prevalence of peri-implant mucositis as a function of these variables were noted with up to three years observation.

Marginal bone loss

Claims of improved clinical outcomes: Marginal bone loss

	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

27 clinical studies related a specific implant characteristic to: Marginal bone loss

	RCTs	CCTs	Other	
Implant geometry	4	3	2	9
Implant material	1			1
Implant surface	3			3
Complex study design	11	3		14
	19	6	2	27

27 clinical studies related a specific implant characteristic to: Marginal bone loss

	RCTs	CCTs	Other	
Implant geometry	4	3	2	9
Implant material	1			1
Implant surface	3			3
Complex study design	11	3		14
	19	6	2	27

Geometry influence has been appraised in 4 RCTs, but with short observation periods and no difference between geometries.

Influence of material has been examined in one split-mouth RCT, with a negative conclusion.

Surface topography influence studied in one RCT and two split-mouth RCTs give inconclusive evidence of specific surface superiority.

27 clinical studies related a specific implant characteristic to: Marginal bone loss

	RCTs	CCTs	Other	
Implant geometry	4	3	2	9
Implant material	1			1
Implant surface	3			3
Complex study design	11	3		14
	19	6	2	27

Several studies where implants/abutments with different geometry, material and surfaces have been evaluated using a RCT design (n=8) and split-RCT design (n=3) failed either to detect significant differences in bone loss or the observation period was too short for making general conclusions about clinical significance.

27 clinical studies related a specific implant characteristic to: Marginal bone loss

	RCTs	CCTs	Other	
Implant geometry	4	3	2	9
Implant material	1			1
Implant surface	3			3
Complex study design	11	3		14
	19	6	2	27

The 3 non-randomised controlled clinical trials suggest that there may be significant differences between different implant brands.

This is also corroborated by two case series reports that focus on a possible influence of implant-abutment geometry on bone loss. However, the possibilities of bias introduced by utilizing less rigorous study designs should be recognized.

Comment – observation methods 1/2

- Reliable bone loss measurements of less than 0.2mm is difficult to achieve, even in in vitro situations
- In many reports the variations in bone loss among the individuals in the study sample varies considerably, as indicated by very large SDs. The SD exceeds, often many times, the differences between implant brands
- This signifies that the relative importance of the implant factor as such is minor in relation to other confounding factors associated with the patient and the clinicians

Comment – observations 2/2

- Short-term results on bone loss require cautious interpretation, especially in studies where one- and two-surgical stages implant systems are being compared
- Short-term studies elucidate the physiological remodeling around implants of different designs
- Do results from short-term clinical studies predict long-term performance of dental implants

Mechanical problems of the implant- abutment-superstructure connections

Claims of improved clinical outcomes: Mechanical problems of the implant-abutment-superstructure connections

	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

- 13 clinical studies related a specific implant characteristic to: Mechanical problems of the implant- abutment-superstructure connections

	RCTs	CCTs	Other	
Implant geometry	1	1	4	6
Implant material	1			1
Implant surface				0
Complex study design	4		2	6
	6	1	6	13

13 clinical studies related a specific implant characteristic to: Mechanical problems of the implant- abutment-superstructure connections

	RCTs	CCTs	Other	
Implant geometry	1	1	4	6
Implant material	1			1
Implant surface				0
Complex study design	4		2	6
	6	1	6	13

The low incidence of mechanical problems reported in the RCTs precludes any general conclusions.

Ceramic abutments may be more prone to mechanical problems than metallic ones during placement, but once this is overcome, the clinical performance is comparable.

13 clinical studies related a specific implant characteristic to: Mechanical problems of the implant- abutment-superstructure connections

	RCTs	CCTs	Other	
Implant geometry	1	1	4	6
Implant material	1			1
Implant surface				0
Complex study design	4		2	6
	6	1	6	13

The limited number of studies using less rigorous and occasionally also retrospectively study designs suggest that the abutment geometry may affect the incidence of mechanical problems over time. However, the possibilities of bias associated with non-prospective study designs should be recognized.

Comment – in vivo study approach

- The very low incidence of mechanical problems calls for very large study samples over a long time span to find meaningful results.
- Thus, the only realistic study design to employ is careful examination of failed implants and/or retrospective data analyses.
- An alternative strategy is to maintain a database of placed and removed dental implants – e.g. Finland

Comment – *in vitro* study approach

- The engineering goal of abutment designing is to provide a ‘fixed joint’ between implant and abutment. I.e. one that can resist all 6 components of force and moment applied to the joint.
- Full data are lacking on exactly what these loading components are in vivo.
- Thus, it remains difficult to assess laboratory testing of abutment systems without knowing the relationship to loads intraorally.
- It is premature to make conclusions about which systems are clinically best without test data linked directly to in vivo conditions.

Mechanical failing of dental implants

Claims of improved clinical outcomes:
Mechanical failing of dental implants

	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

- 4 clinical studies related a specific implant characteristic to: Mechanical failing of dental implants

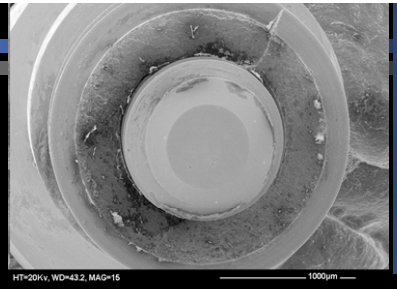
	RCTs	CCTs	Other	
Implant geometry			2	2
Implant material	1			1
Implant surface	1			1
Complex study design				0
	2	0	2	4

4 clinical studies related a specific implant characteristic to: Mechanical failing of implant

	RCTs	CCTs	Other	
Implant geometry			2	2
Implant material	1			1
Implant surface	1			1
Complex study design				0
	2	0	2	4

The findings provide little information on the possible relationship between implant characteristics and mechanical failing of the implant.

Comment



- Technical failures of implants are relatively sparsely described in the literature.
- Contrast the more common fractures of abutment screws and prosthetic screws
- Overload seems not to be an aetiological factor as a cause for implant fracture clinically.

General aspects of the clinical performance of implants

General aspects of the clinical performance of implants

- Sudden loss of osseointegration is usually unexpected, and is often not preceded by any clinical observable special event.
- Due to the operation team or operator, the patient, the supraconstruction or the actual Implant?

General aspects of the clinical performance of implants - operator

- Inherent danger in limiting the focus of qualitative patient care to just the actual dental implant hardware.
- Surgical skills may be more important for clinical success than differences in implant characteristics
- Many clinical studies report a significant influence on the results depending on the skills of the surgeon - erroneous treatment planning or actual handling skills

Is the major effect due to the operation team, the patient, or the actual Implant?

- Operation team include wrong indication or neglect of contra-indications, lack of experience, or the prevailing implant culture (implant selection, operation technique, inadequate equipment or staff, decisions during the operation and treatment, neglect of signals received during follow-up, neglect of systematic follow-up).

General aspects of the clinical performance of implants - patient

- From a clinical or microbiological perspective, implant failures seem primarily to be at a patient level rather than at an implant level.
- Thus, even tangible and intangible patient aspects may be more relevant etiological factors in implant failure than the actual implant hardware and the operator.

- Is the major effect due to the operation team, the patient, or the actual Implant?
  - Patient-related reasons include medical condition before operation, smoking, accidents or perhaps irresponsible use of implant and neglect of home care.

General aspects of the clinical performance of implants - hardware

- Do some implant brands contain ‘technique sensitive characteristics’?
- Confound the issue of whether it is inadequate training or implant characteristics that explain the lack of success in the hands of other operators or when moving from delayed to earlier loading?

- Is the major effect due to the patient, the operation team, or the actual Implant?
  - Potential failures due to the implant per se may include inadequate design of the implant, raw material imperfection, manufacturing defects, and deficiency in sterilising and storing.

Other effect factors besides the implant hardware - suprastructure

- Fixed versus removable?
- Number of implants for support?
- Cemented versus screw-retained?
- Attachment systems?
- Material used?
- Unpredictable loading due to misfit?

Considerations for future research

Considerations for future research – 1/3

- Confusion regarding which implant characteristic should be considered to be clinically important until comparative trials
- Few clinical studies that have mostly compared different implant brands, whereby the influence on outcome due to implant geometry, material and surface topography is confounded.

Considerations for future research – 2/3

Ethical dilemma in comparing implants

- A hypothesis that better treatment is offered than the best documented results available, to justify a comparison in vivo.
- The documented implant brands all show very good results with almost no serious complications.
- Hence, a significant number of subjects are needed to separate one implants.

Considerations for future research – 2/3

- New trials should preferably compare positive effects/outcomes, in contrast to the more common analyses of the adverse biological and mechanical problems (i.e. when the failures are counted under the assumption that the non-failures are survivals).

Considerations for the practicing dentist

Nine considerations for the practicing dentist:

1. Is the manufacturer represented locally and can be consulted easily?
2. Can they deliver required products timely and reliably in extraordinary situations?
3. The manufacturer's ethical and professional reputation. Is the manufacturer's promotion exact, fair and comprehensive?
4. Does the manufacturer provide service and training possibilities?

Nine considerations for the practicing dentist:

5. Ease of use. Are the training requirements for using the implant system intricate?

6. Flexibility of applications. ? alternative prosthodontic options such as o-rings, attachments and choice of screw retained or cemented supraconstructions, possibility for cast and cemented abutments, angled abutments and anti-rotational abutments?

Nine considerations for the practicing dentist:

7. Stock inventory. Is it necessary for the dentist to acquire an extensive supply of hardware to meet different treatment situations and thereby induce high inventory costs?
8. Engineering design. Since mechanical defects will occur sooner or later, are elaborate and/or time-consuming techniques necessary in order to make adjustments or remakes?

Nine considerations for the practicing dentist:

9. Costs ?
   - Surgical and prosthetic start-up kit,
   - Per implant and per component,
   - Course/training costs
   - Accumulated time required for adjustments and mechanical failures
   - Involves patient trust and opportunity cost.

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ON-LINE REGISTRATION!!

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

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.

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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.

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- 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.
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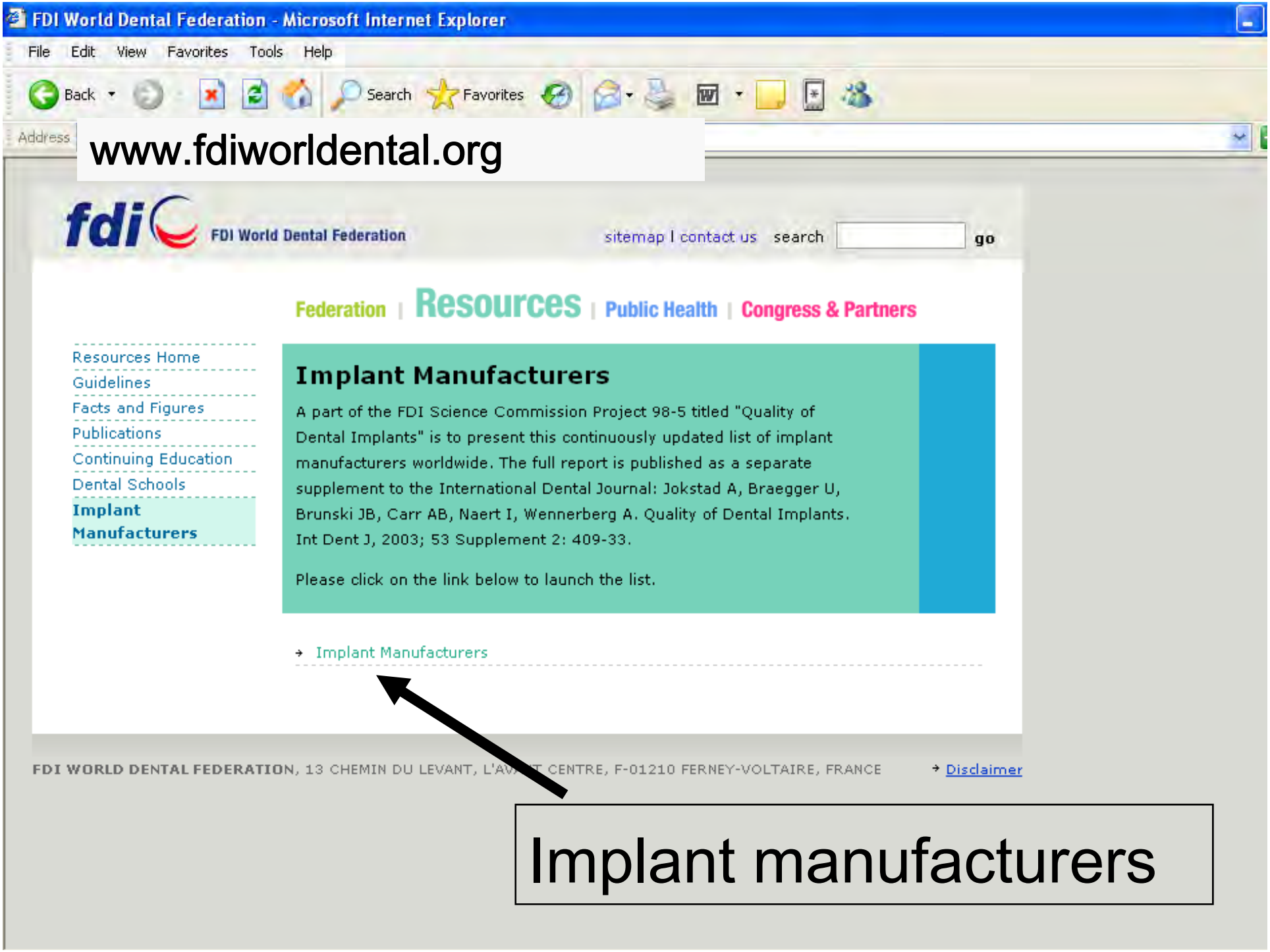
Submitted by: FDI Science Committee

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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File Edit View Favorites Tools Help
Back Search Favorites
Address
www.fdiworldental.org
fdi FDI World Dental Federation
sitemap | contact us search go
Federation | Resources | Public Health | Congress & Partners
Resources Home
Guidelines
Facts and Figures
Publications
Continuing Education
Dental Schools
Implant Manufacturers
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'AVANT CENTRE, F-01210 FERNEY-VOLTAIRE, FRANCE
Disclaimer
Implant manufacturers

Quality of Dental Implants*

Asbjørn Jokstad[a]/Urs Braegger[b]/John B. Brunski[c]/Alan B. Carr[d]/Ignace Naert[e]/Ann Wennerberg[f]

Background: Clinicians need quality research data to decide which dental implant should be selected for patient treatment. ***Aim(s)/Objective(s):*** To present the scientific evidence for claims of relationship between characteristics of dental implants and clinical performance. ***Study Design:*** Systematic search of promotional material and Internet sites to find claims of implant superiority related to specific characteristics of the implant, and of the dental research literature to find scientific support for the claims. ***Main Outcome Measures:*** Critical appraisal of the research documentation to establish the scientific external and internal validity as a basis for the likelihood of reported treatment outcomes as a function of implant characteristics. ***Results:*** More than 220 implant brands have been identified, produced by about 80 manufacturers. The implants are made from different materials, undergo different surface treatments and come in different shapes, lengths, widths and forms. The dentist can in theory choose among more than 2,000 implants in a given patient treatment situation. Implants made from titanium and titanium alloys appear to perform well clinically in properly surgically prepared bone, regardless of small variations of shapes and forms. Various surface treatments are currently being developed to improve the capacity of a more rapid anchorage of the implant into bone. A substantial number of claims made by different manufacturers on alleged superiority due to design characteristics are not based on sound and long-term clinical scientific research. Implants are, in some parts of the world, manufactured and sold with no demonstration of adherence to any international standards. ***Conclusions:*** The scientific literature does not provide any clear directives to claims of alleged benefits of specific morphological characteristics of dental implants. *Int J Prosthodont 2004;17:607–641; reprinted with permission from Int Dent J 2003;53:409–443.*

Clinicians have for many decades attempted to replicate teeth by implanting alloplasts into bone. Scientifically based implant therapy, however, emerged at the end of the 1970s following groundbreaking studies with 10-year clinical results presented by a research group in Sweden directed by Dr Per-Ingvar Brånemark.[1,2] Their studies demonstrated conclusively that pure titanium integrates with bone tissue if it is carefully prepared surgically, and that a transmucosal element (abutment) joined to the implant can retain an intraoral prosthesis with a predictable clinical outcome. During the years since these discoveries, there has been a proliferation of manufacturers who produce implants using various biomaterials and surface treatments. These are termed oral or dental implants, but the two terms are in practice regarded as synonyms. Dental implants vary in material, dimensions, geometries, surface properties and interface geometry,[3,4] so today the dentist needs to select from more than 2,000 different dental implants and abutments in a specific

[a]Professor, Oslo, Norway.
[b]Professor, Bern, Switzerland.
[c]Professor, Troy, Minnesota.
[d]Professor, Rochester, Minnesota.
[e]Professor, Leuven, Belgium.
[f]Professor, Gothenburg, Sweden.

Correspondence to: Prof Asbjørn Jokstad, Institute of Clinical Dentistry, University of Oslo, PO Box 1109 Blindern, N-0317 Oslo, Norway. e-mail: jokstad@odont.uio.no

**Report initiated by and document approved by FDI Science Commission. Reprinted from the International Dental Journal (2003;53:409-443) with kind permission of the Editor.*

Commentaries: Quality of Dental Implants

Lyndon Cooper
University of North Carolina
Chapel Hill, North Carolina, USA

At a point in the evolution of dental implant therapy when hundreds of implant brands and countless variations of implant design exist, the astute clinician must evaluate claims made by the manufacturers, the investigators sharing outcome data in peer-reviewed journals, as well as the clinical experts who offer insight through alternative publications or podium presentations. In "Quality of Dental Implants," our colleagues provide an important evaluation of the relationship between existing data concerning dental implant performance and various claims made regarding different implant design features.

The scope of this report is striking. Summarizing, logically collating diverse data sets, and ranking the data according to scientific rigor represents an enormous task. This effort implicitly argues that defining implant quality is an important part of our professional obligation and defines the shared commitment of prosthodontists to excellence of comprehensive dental rehabilitation using dental implants.

Jokstad and colleagues selected seven clinical outcomes that were considered in the context of six sets of dental implant design features. Whether we agree with the chosen outcomes or the precise design features chosen, the work is exhaustive and serves to indicate at least two important points. First, a clinical study that is specifically designed to measure one or more of these specific outcomes is both complex and difficult to perform well. Second, the quality of existing data sets ranges from good to poor with few randomized prospective comparative clinical trials of sufficient size to provide statistical power to adequately test superiority regarding one or another implant design parameter.

A third and important general observation made from compilation of this data set is that only a very few dental implant manufacturers are engaged in creation of this important data set. What this means to one reader or another is appropriately left unstated, and is one important point that every reader must consider in providing patient care.

Can the reader accept the conclusion that "several implant systems appear comparable"? One interpretation is that this statement is true in the context of the suggested limitations of data. Alternatively, given the limitations in data ("the scientific evidence of the influence of dental implant materials, geometry and surface topography on clinical performance is limited and not particularly methodologically sound"), particularly the lack of studies designed specifically to compare one design feature to another, it can be argued that the impact of implant design features on the practice of dental rehabilitation remains an important unresolved issue of merit.

What do implant design features offer the practicing clinician and what potential benefits are derived by the patient? Optimism requires believing that improved clinical control of outcomes will be derived from changing implant design features. Caution requires data supporting new theories be tested first in the laboratory, second in preclinical studies, and ultimately in controlled clinical studies prior to widespread use. "Quality of Dental Implants" offers an important source of information, raises important questions, and provides a focal point for considering the products in the dental implant marketplace.

What about the new Implant systems and quality of promotional material?

How many new implant brands have been introduced since Oct 2003?

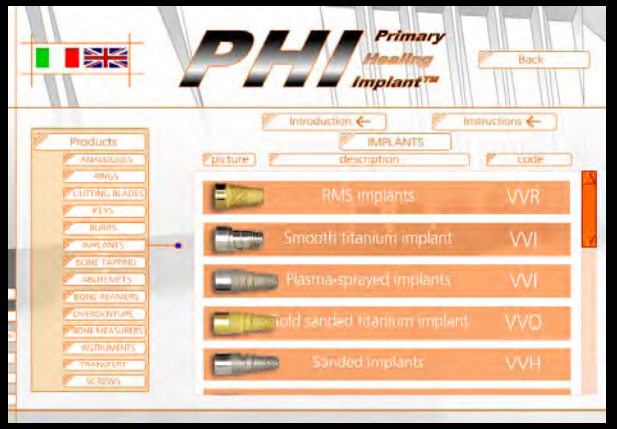
A: approx. 20

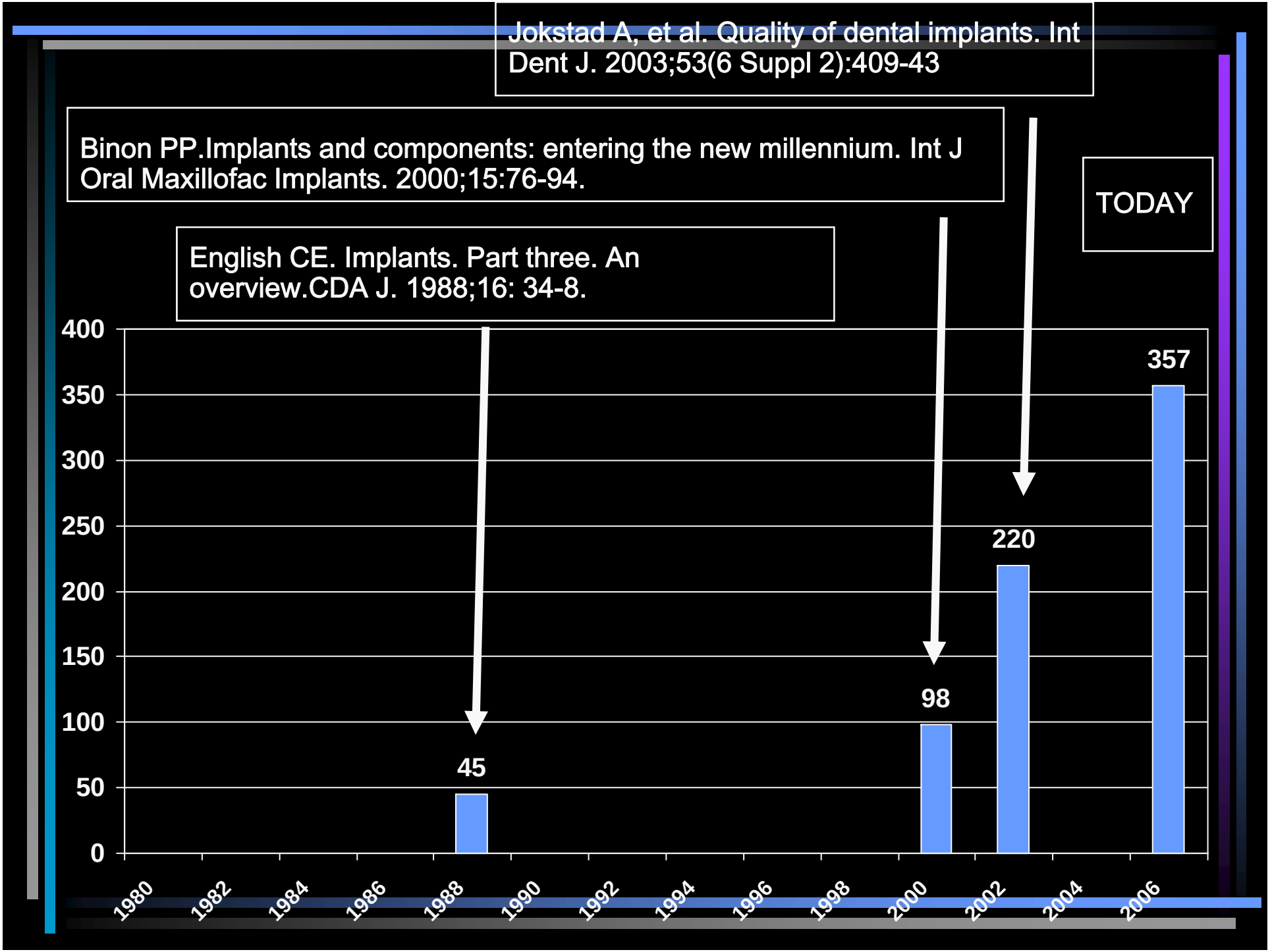
B: approx. 50

C: approx. 75

D: approx. 100

E: approx. 150




Jokstad A, et al. Quality of dental implants. Int Dent J. 2003;53(6 Suppl 2):409-43
Binon PP.Implants and components: entering the new millennium. Int J Oral Maxillofac Implants. 2000;15:76-94.
English CE. Implants. Part three. An overview.CDA J. 1988;16: 34-8.
TODAY
400
350
300
250
200
150
100
50
0
45
98
220
357
1980
1982
1984
1986
1988
1990
1992
1994
1996
1998
2000
2002
2004
2006

Oct 2003: 78 implant manufacturers.
How many do we have today?

A: approx. 80

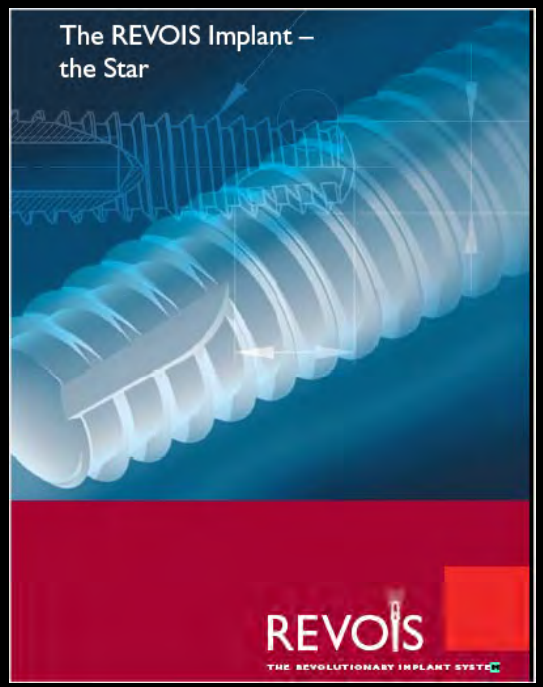
B: approx. 90

C: approx. 100

D: approx. 110

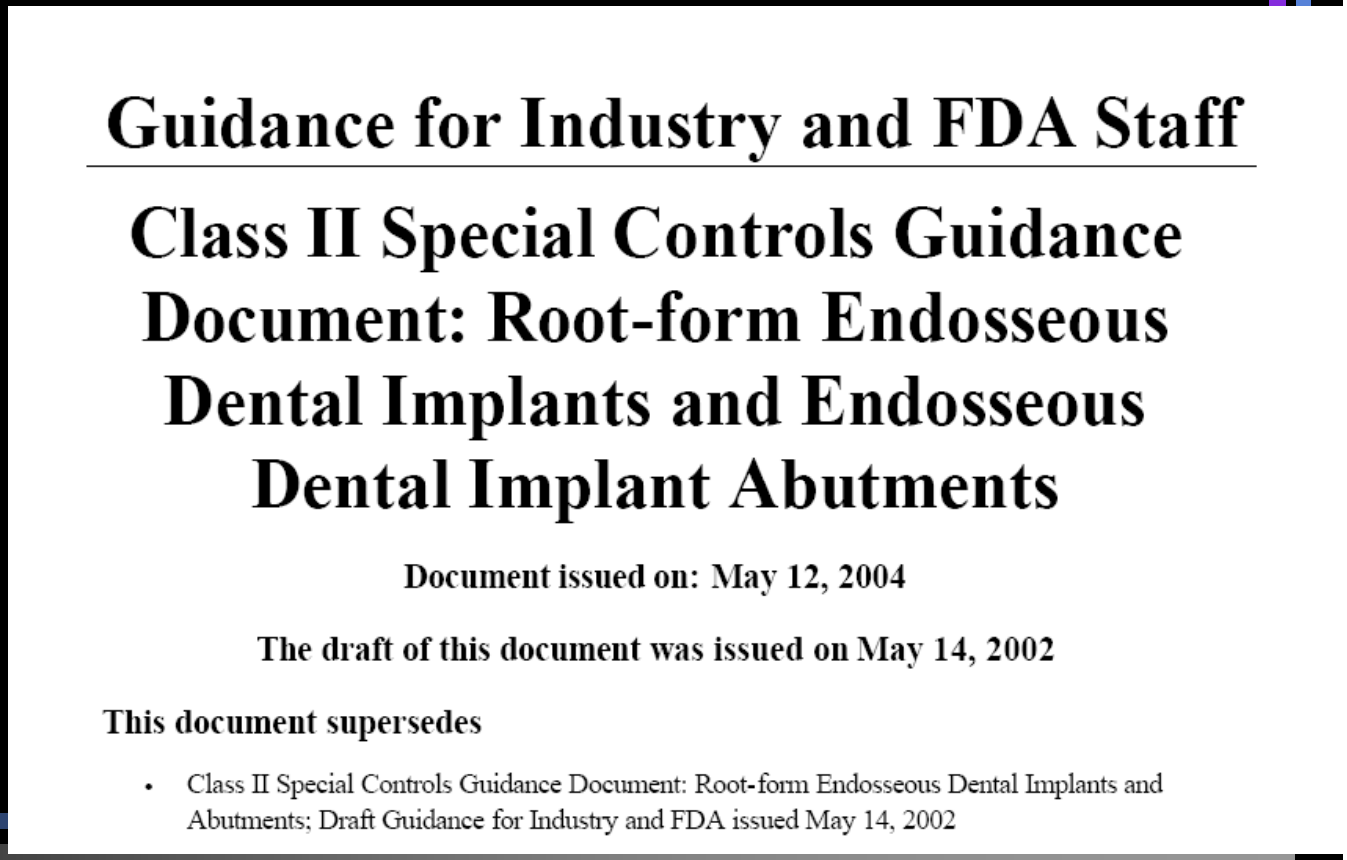
E: approx. 120

*" 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…"*



What about regulatory and standardization changes?

- FDA ?



Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments

Document issued on: May 12, 2004

The draft of this document was issued on May 14, 2002

This document supersedes

- Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA issued May 14, 2002

The "Groovy implant"

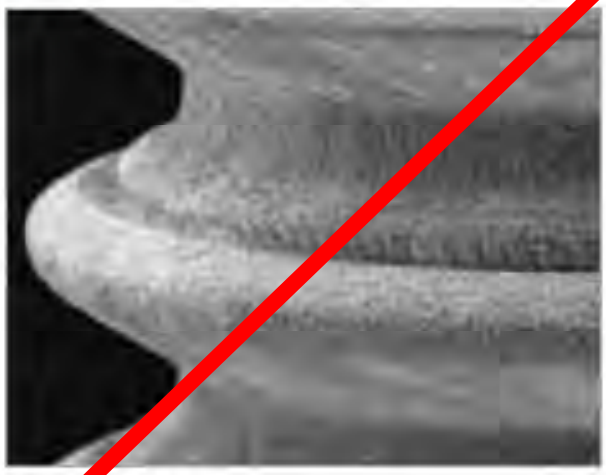
Benefits of Grooves Incorporated onto the Thread of the Implant:

- 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

30%

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.



> 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.

Page 33. In: Nobel Biocare. *Annual report* 2005

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http://www.fda.gov/cdrh/pdf5/K050258.pdf Go Links Google 510k nobel biocare groovy

Select Text 112%

APR 19 2005

K050258

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Herbert Crane Manager, Regulatory Affairs
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

8,64 x 11,36 in

1 of 4

Internet

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

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

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Hall J, Miranda-Burgos P, Sennerby L.

Nobel Biocare AB, Goteborg, Sweden. jan.hall@nobelbiocare.com

Purpose: *Study if bone formation and implant stability were influenced by 110 □m and 200 □m and 70 □m deep grooves positioned at a thread flank*

M&M: 18 rabbits – 6 x 7 mm implants

9: 3 control impl. + 3 test impl. (110 □m wide & 70□m deep)

9: 3 control impl. + 3 test impl. (200 □m wide & 70□m deep)

6 weeks □ Removal torque (RTQ) (2 control impl. vs 2 test impl.)

□ Histology (1 control impl. vs 1 test impl.) "bone-fill"

Results:	RTQ	% bonefill	
110x70 □m grooves	+30% p< 0.05 (36)	p< 0.05 (18)	vs. control
200x70 □m grooves	+ 8% p< 0.05 (36)	p< 0.05 (18)	vs. control

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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

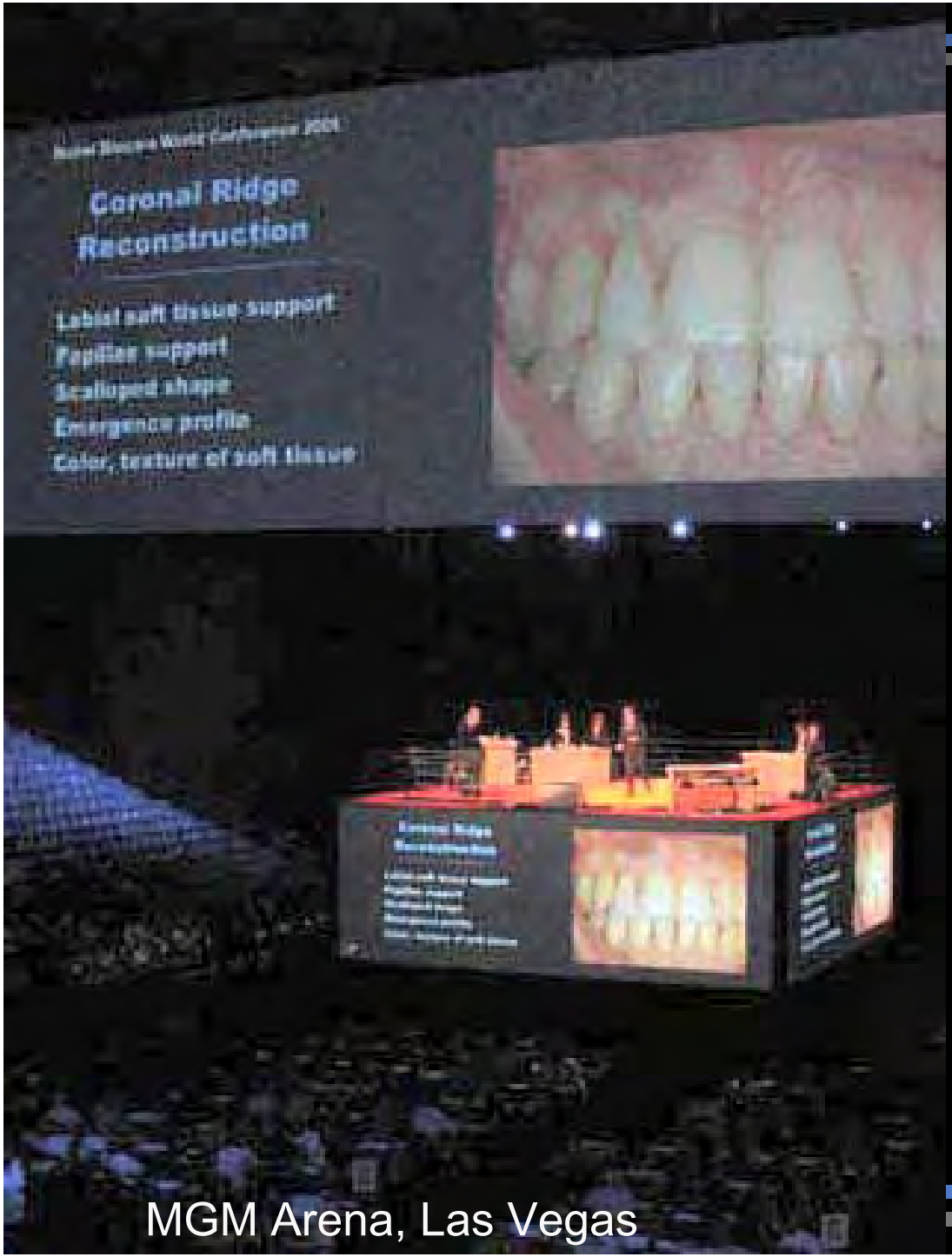
APR 19 2005

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

19. April 2005:
510K Approval

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.



MGM Arena, Las Vegas

2 Feb 2005:
Application

19 April 2005:
Approval

6 June 2005:
World Premiere!

Stimulation of Directed Bone Growth at Oxidized Titanium Implants by Macroscopic Grooves: An In Vivo Study

Jan Hall, MSc;* Patricia Miranda-Burgos, DDS;† Lars Sennerby, DDS, PhD†

ABSTRACT

Background: The influence of thread design at the
bone integration and the stability of dental implan
influence of implant structures in the range of 50 to

Purpose: The present in vivo investigation was unde
by 110 (S1) and 200 (S3) µm–wide and 70 µm–deep

Materials and Methods: Eighteen rabbits and oxidize
in the study. Nine rabbits received three control in
one thread flank. The remaining nine rabbits receiv
groove. The animals were followed for 6 weeks. Re
leg. The remaining implant per leg was retrieved for
ing bone formation at the opposing surfaces, the b
were calculated for each implant.

Results: The histologic analyses revealed an affinity for bone formation within the grooves. The RTO tests sho

TABLE 2 Results from Histomorphometric Measurements of Tibial Specimens

Parameter	S1	C_{S1}	*p* Value
Bone area, %	13.9 ± 8.3	8.9 ± 7.6	NS
Bone contact, %	24.7 ± 16.1	20.2 ± 8.6	NS
Parameter	**S3**	**C_{S3}**	***p* Value**
Bone area, %	12.8 ± 4.1	7.0 ± 4.5	NS
Bone contact, %	26.4 ± 15.8	18.6 ± 9.9	NS

C = control.

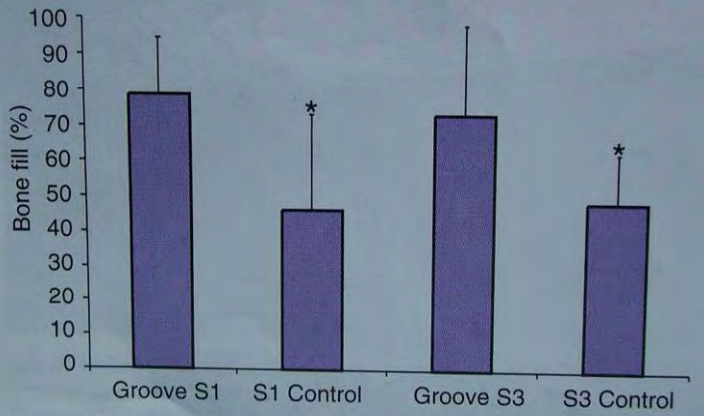
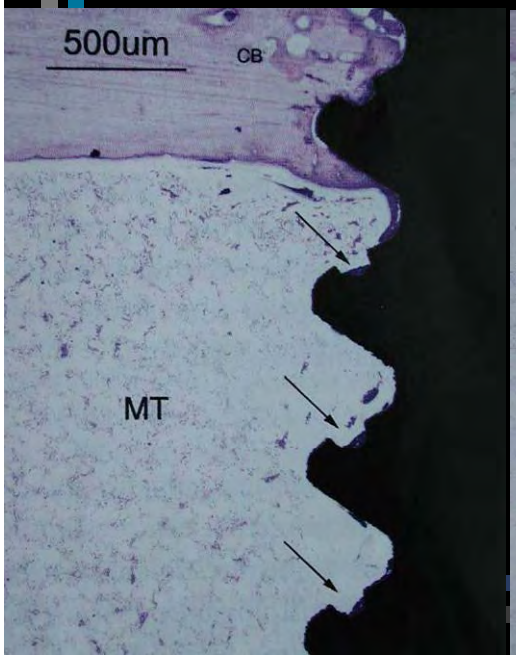
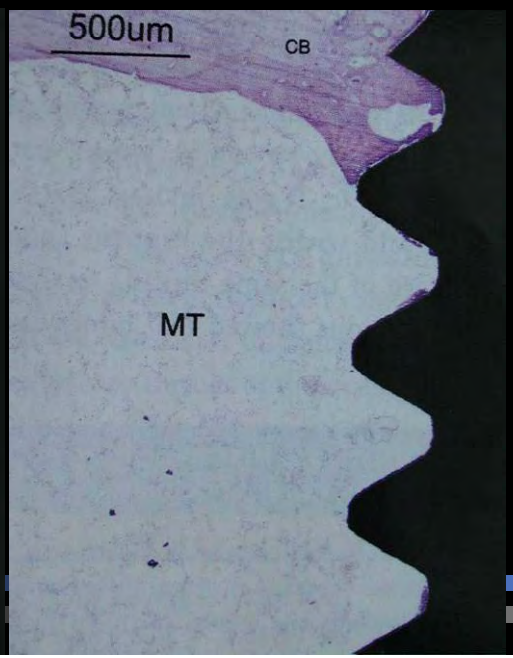


Figure 5 Graph showing bone fill in grooves and opposing surfaces as calculated for all threads.* $p < .05$





CONCLUSION

It is concluded that 110 and 200 µm–wide and 70 µm–deep grooves at oxidized implant surfaces stimulate bone to preferentially form within and along the groove in the rabbit model. The 110 µm–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 further optimize implant stability in suboptimal clinical conditions.

Stimulation of Directed Bone Growth at Oxidized Titanium Implants by Macroscopic Grooves: An In Vivo Study

Jan Hall, MSc;* Patricia Miranda-Burgos, DDS;† Lars Sennerby, DDS, PhD†

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Materials and Methods: Eighteen rabbits and
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one thread flank. The remaining nine rabbit
groove. The animals were followed for 6 we
leg. The remaining implant per leg was retrie
ing bone formation at the opposing surface
were calculated for each implant.

Results: The histologic analyses revealed an

TABLE 1 Results from Removal Torque Measurements

Site	S1	C_{S1}	Difference, %	*p* Value
Tibia	37.3 ± 10.2	30.4 ± 10.5	30.4 ± 33.8	.04
Femur	63.1 ± 17.0	50.6 ± 12.2	26.6 ± 28.1	NS
Pooled	46.7 ± 12.9	37.2 ± 10.2	25.5 ± 21.2	.04
	S3	**C_{S3}**	**Difference, %**	***p* Value**
Tibia	34.7 ± 10.1	32.3 ± 6.7	8.3 ± 25.8	NS
Femur	63.3 ± 12.8	59.2 ± 12.2	7.7 ± 16.1	NS
Pooled	49.0 ± 10.2	45.8 ± 7.9	7.3 ± 14.6	NS

C = control; NS = not significant.
Mean values in Newton-centimeters and differences in percent $[(Sx - C_{sx})/C_{sx}*100]$.

CONCLUSION

It is concluded that 110 and 200 µm–wide and 70 µm–deep grooves at oxidized implant surfaces stimulate bone to preferentially form within and along the groove in the rabbit model. The 110 µm–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 further optimize implant stability in suboptimal clinical conditions.

What about the clinical documentation of new implant systems?

Cochrane Oral Health Group

Since 2000

11 systematic reviews completed on osseointegrated dental implants. Esposito M, Coulthard P, Worthington H, Thomson P / (Jokstad A) (Wennerberg A)

2 SR protocols (Jokstad A, Carr A, Esposito M, Coulthard P, Worthington H)

Interventions for replacing missing teeth: partially absent dentition

Interventions for replacing missing teeth: totally absent dentition

How many clinical trials on dental implants are published per year?

A: approx. 40

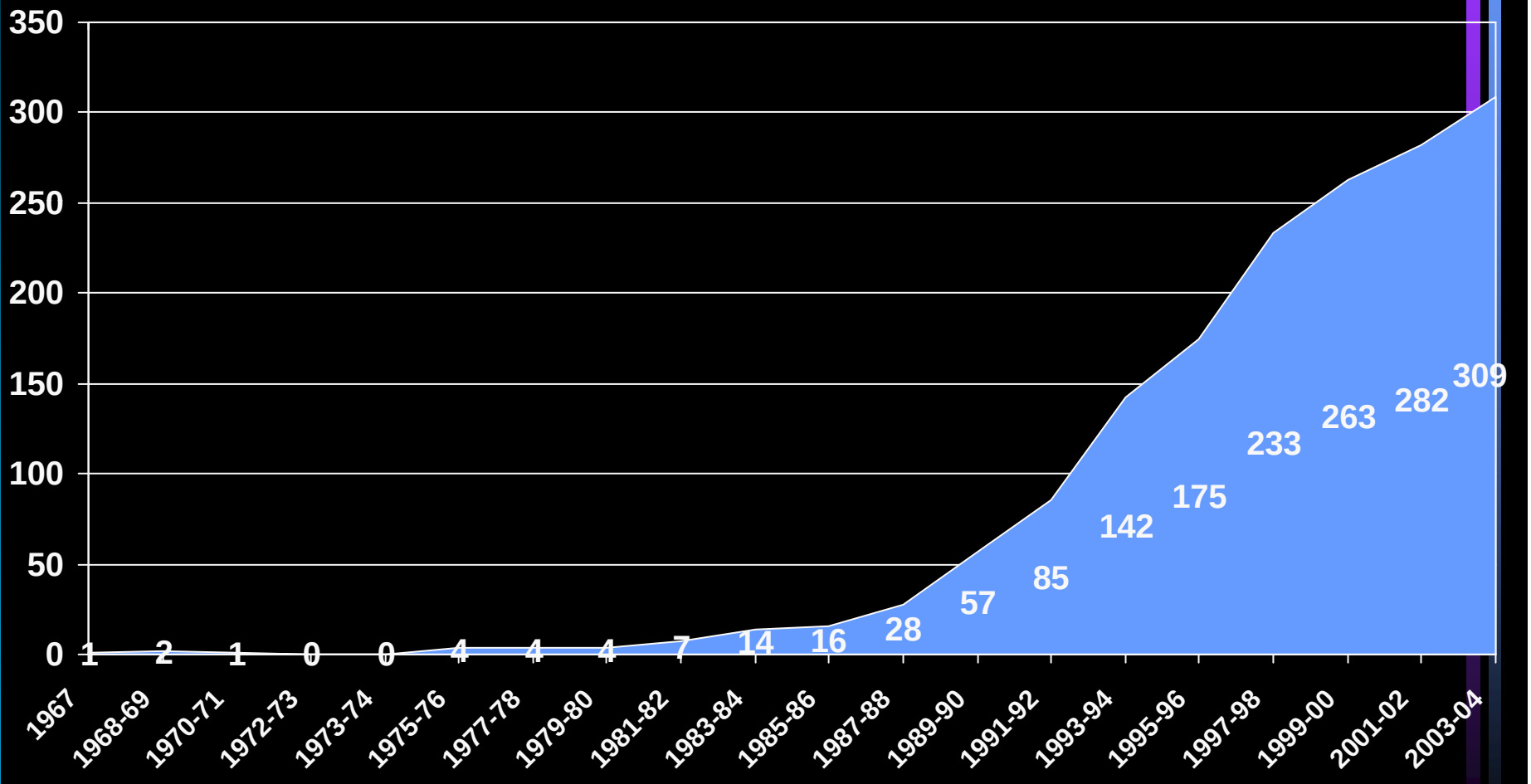
B: approx. 80

C: approx. 120

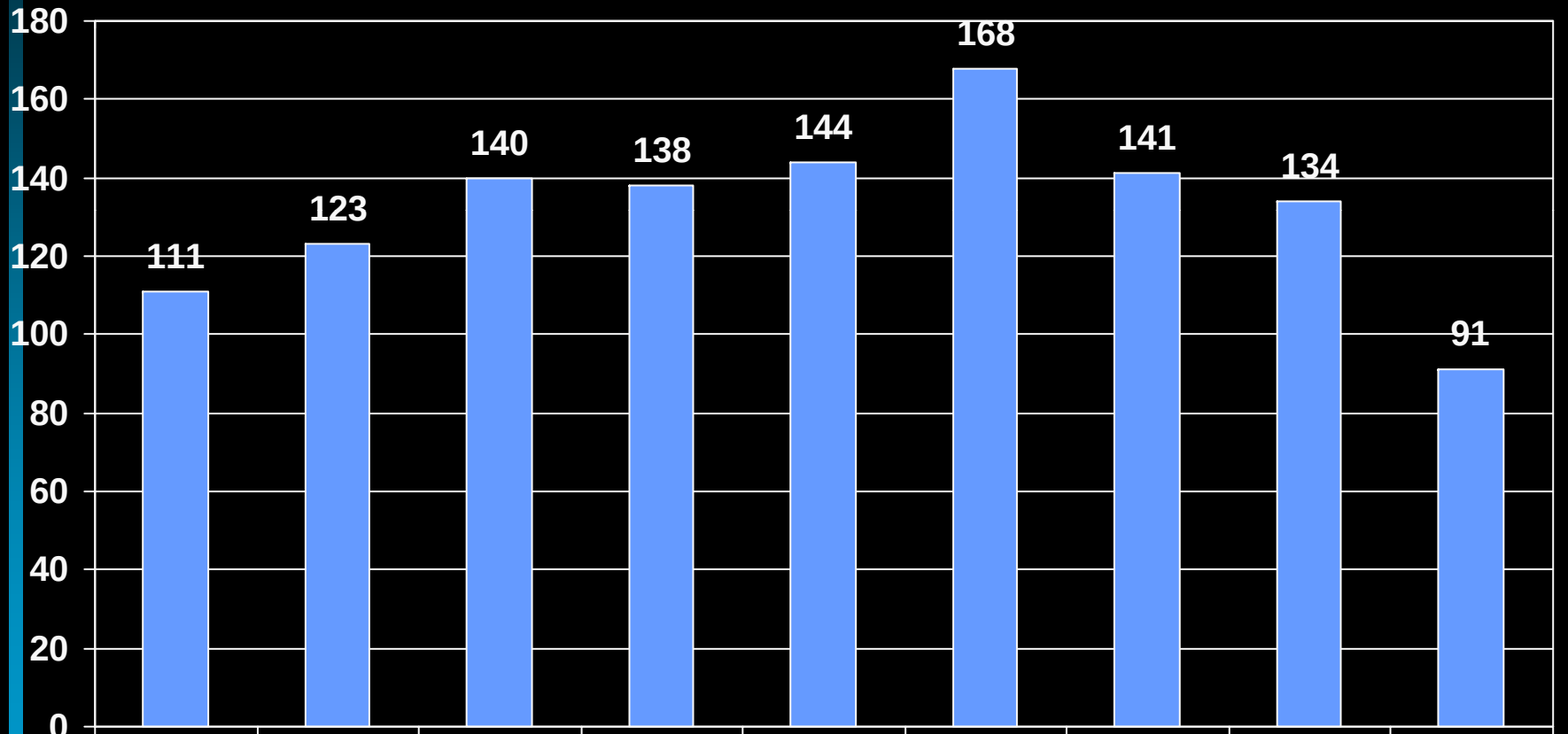
D: approx. 160

E: approx. 200

Clinical trials – Dental implants



Clinical trials – Dental implants



Clinical trials – Dental implants

Clinical trials since 2003 = 362

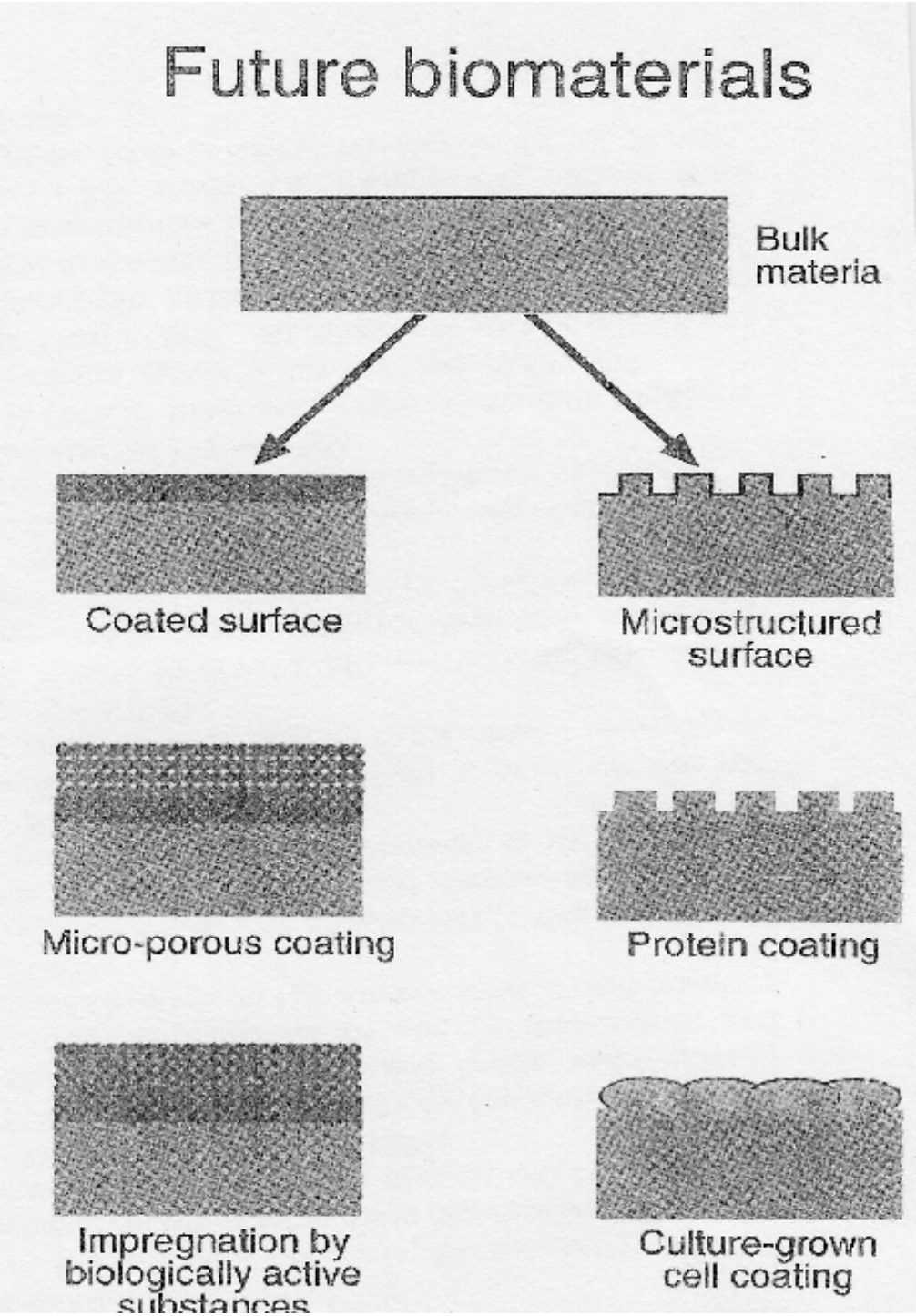
- 3i/Osseotite 34
- Astra 18
- Branemark 122
- Frialit2/Frialit+/Frialoc/Frios 23
- ITI /Straumann 79

267 (73%)

Implant characterization

- Systems for classification can be constructed according to morphological differences.
- But- the concept of such classification systems and construct of subcategories needs to reflect clinically relevant data in order to be meaningful.
- Since we still lack this basic knowledge it remains difficult to establish a valid categorization system for dental implants.

KASEMO &
GOLD 1999

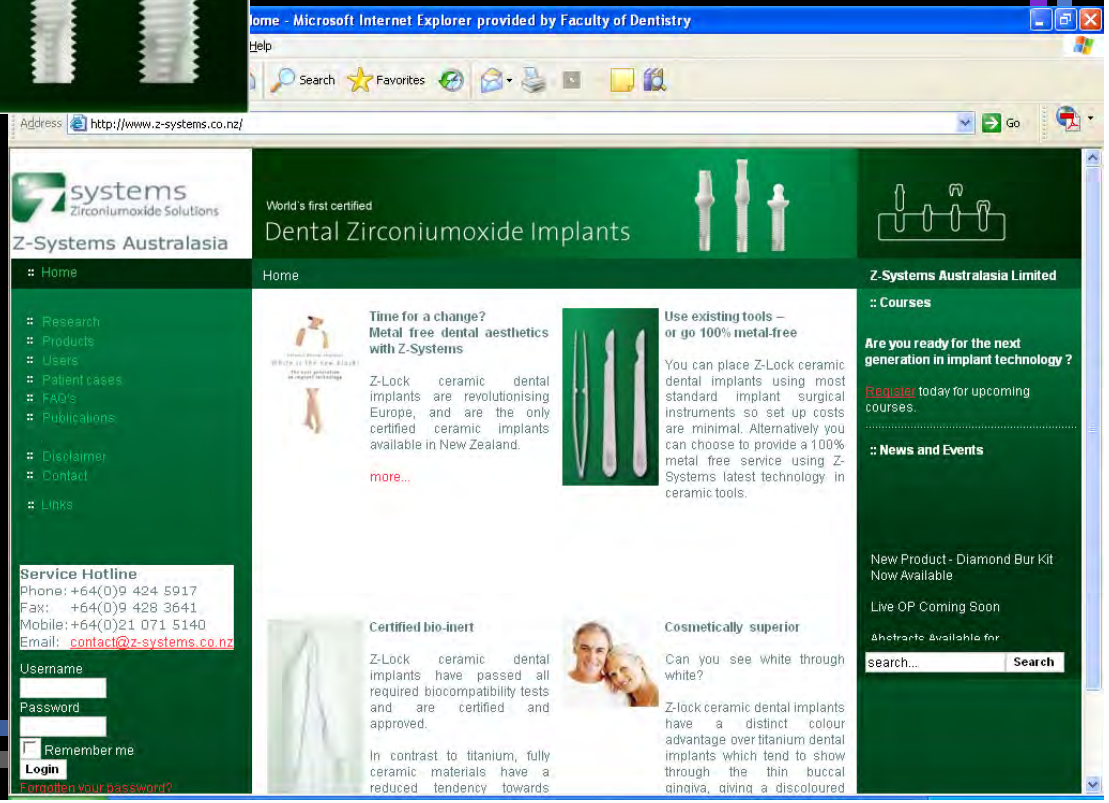


Implant characterization

- The validity of in vitro studies to predict clinically significant improvements remains uncertain

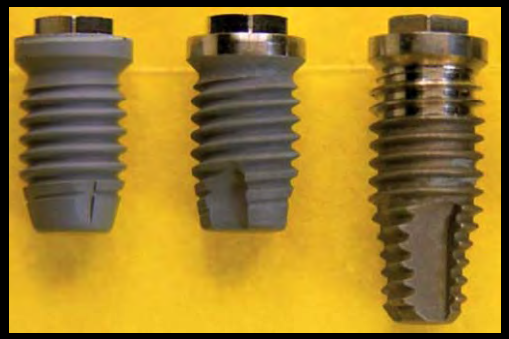
What is the clinical relevance of animal models for evaluating bone & cell responses *vz* implant design & roughness?

Implant material

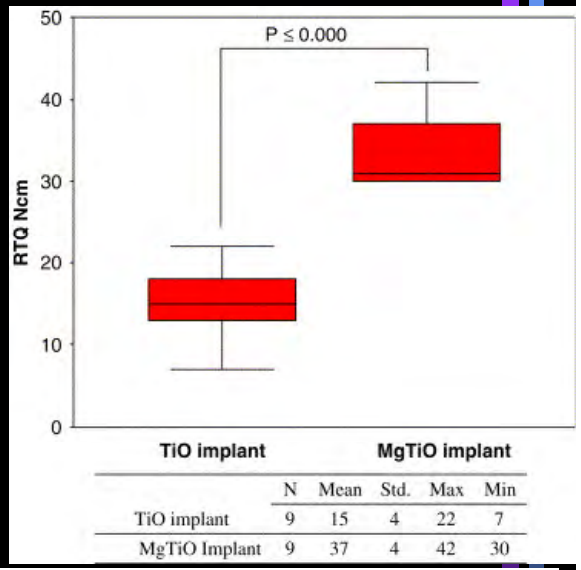


Implant surface treatment

- Magnesium ion incorporated, oxidized implants ? Dr Young-Taeg Sul - Korea

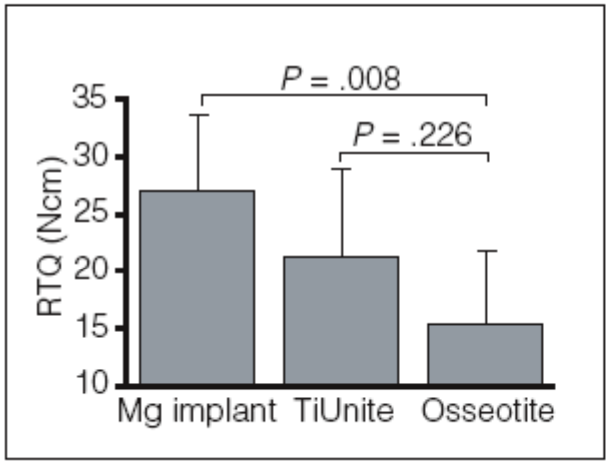


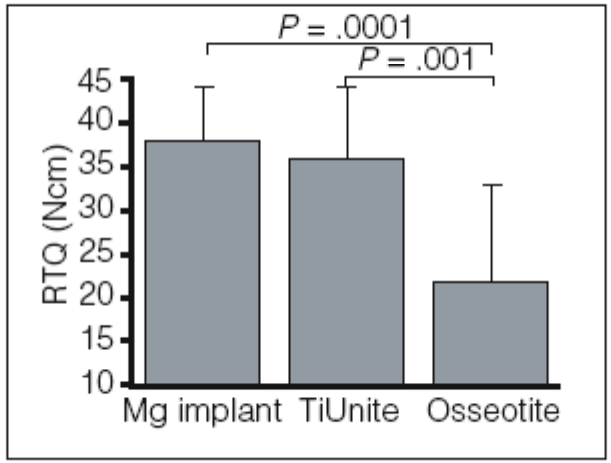
Sul YT, et al. Biomaterials. 2005 Nov;26(33):6720-30

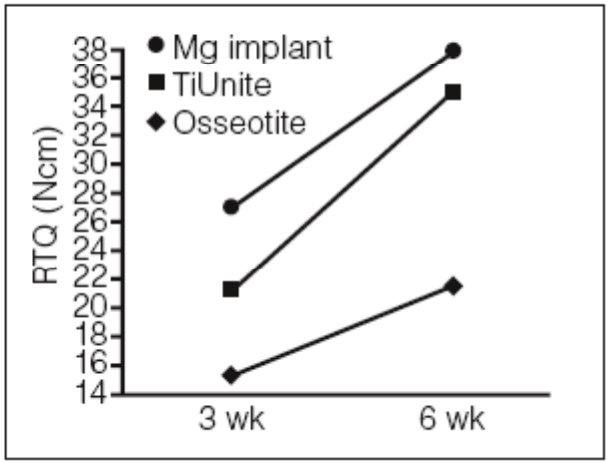


	N	Mean	Std.	Max	Min
TiO implant	9	15	4	22	7
MgTiO Implant	9	37	4	42	30

Sul YT, et al. Int J Prosthodont. 2006;19:319-28





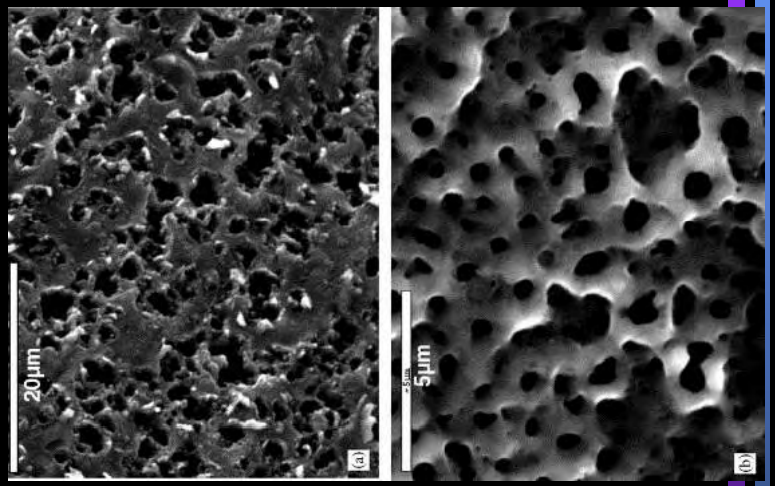


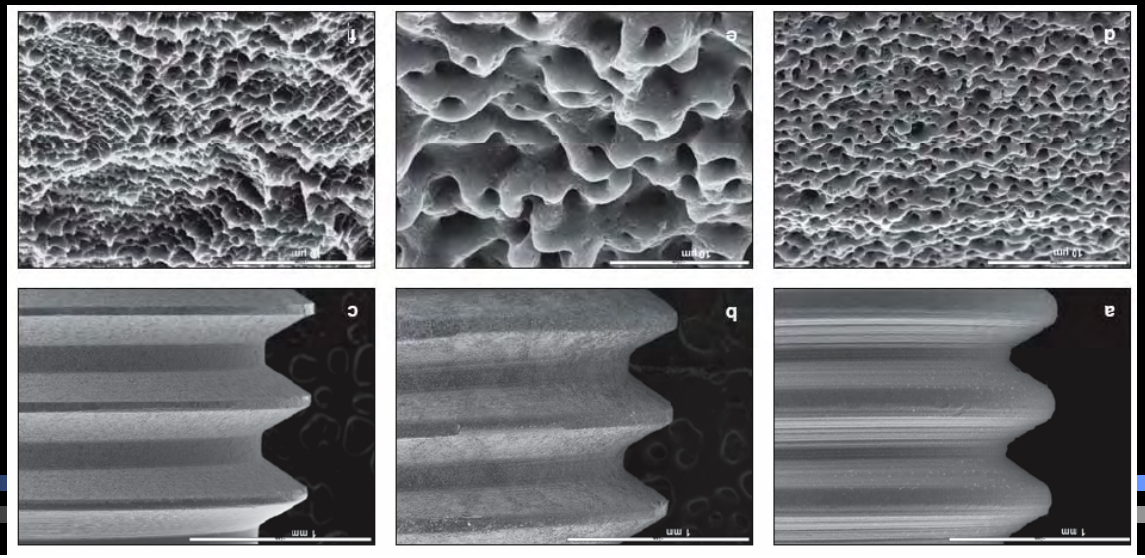
Implant surface treatment

- Magnesium ion incorporated, oxidized implants ? Dr Young-Taeg Sul - Korea

Sul YT, et al. Biomaterials. 2005 Nov;26(33):6720-30

Sul YT, et al. Int J Prosthodont. 2006;19:319-28





Thank you for your kind attention