International Dental Journal (2003) **53**, 000-000

Quality of dental implants*

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

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 root formed 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 root-formed dental implants.

Key words: Implantology, systematic review, dental industry, evidence-based dentistry

*Report initiated by and document approved by FDI Science Commission.

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

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-years clinical results presented by a research group in Sweden directed by Dr Per-Inge 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 treatment situation. Certain manufacturers alone offer more than 100 different implants in varying shapes and materials. Other manufacturers focus in their promotional material on seemingly significant advantages in implant characteristics, but without relevant clinical support of the claims. The bewildered clinician is left with the question of which

0020-6539/03/06000-35

criteria one should employ to differentiate between good and bad quality.

Dental implants, characteristics

A careful surgical technique is strongly associated with a successful treatment outcome, at least for the early post-insertion period, but implant-specific features should be considered important as well. In addition to the actual material composition, at least two morphological characteristics may be relevant, namely the implant's geometry and the surface topography[2].

Implant material

The majority of dental implants today are made from commercially pure (c.p.) titanium or titanium alloys. A smaller group of implants are made entirely out of, or surface-coated with, a complex of calcium phosphate, of which the most common is hydroxyapatite (HA). Other implants that have been commercially available previously composed of materials such as aluminium oxide, 'bioglass', 'crystal' and 'vitreous carbon' have now more-or-less disappeared. C.p. titanium is produced with various degrees of purity, which is important for, for example, airplane manufacturers.

Basically, the maximum oxygen percentage defines the commercially pure grade of titanium according to an American standard (ASTM F67). C.p. titanium grade 1 has the highest purity because of its low oxygen and iron content versus c.p. titanium grade 4, which has the highest maximum oxygen and iron percentage. Implants are made from the full range of different c.p. titanium grades. For example, Brånemark system® implants (Nobel Biocare, Sweden) are made from grade 1 c.p. titanium, while ITI® implants (Straumann, Switzerland) are made from grade 4 c.p. titanium. Titanium alloys are designed with ASTM grades from 5 to 29, and several manufacturers use the grade 5 titanium alloy, often designed Ti-6Al-4V, for dental implants (e.g. Sargon®, Sargon Enterprises, USA). In general, c.p. grade 1 titanium demonstrates the highest corrosion resistance and lowest strength, while grade 4 (titanium) and grade 5 (titanium alloy) demonstrate greater yield strengths. As the corrosion resistance is almost entirely dependent upon the iron content, several dental implant manufacturers (e.g. Astra Tech, Sweden) use grade 4 titanium where the iron content is limited to below the maximum allowed in grade 1. The direct implications of the relatively small differences in mechanical and physical properties on the clinical performance intraorally are uncertain, e.g. the relationship between tensile or fatigue strength and the incidence of mechanical complications over time[5].

Implant geometry

Root formed dental implants have been designed in a wide variety of body geometries. The implants were previously categorised as screw, cylinder and hollow basket types. Today, the last group is regarded as obsolete and the distinction between the screw type, i.e. having threads, and the cylinder type is becoming blurred. The terms threaded and non-threaded implants are often used as synonyms for screw and cylinder implants. Both screws and cylinders are manufactured with straight, tapered, conical, ovoid or trapezoidal walls. Variations in the form of the threads, supplementing vents, grooves and steps increase the complexity of characterising implants by geometries. There even exist implants designed to expand the apical part after placement into the prepared bone tissues. A trend seems to exist towards producing implants with three-dimensional morphology that alters along the vertical axis. *Figure 1* illustrates the wide variation in geometries of root formed implants. In addition, some dentists place trans-mandibular, blade, or frame implants, but in very small numbers and these will not be described further in this report. Sub-periosteal and sub-mucosal implants are today regarded as obsolete.

Implant surface topography

Different methods are being used to alter the surface topography of dental implants. One or several of these methods are used to produce either an isotropic surface (i.e. with surface asperities that are randomly distributed so the surface is identical in all directions) or an anisotropic surface (i.e. surface with a directional pattern) (*Table 1*). The surface treatments are suggested to improve the capacity of anchorage into bone. It has been postulated, mostly on basis of animal and histological studies, that this advantage can be seen in an early healing phase in comparison with a turned surface[6,7].

The predictability for an acceptable treatment outcome has been shown to be very good for implants machined with a turning process[8,9]. The clinical outcome of other various surface modifications has also been published to different extent. Most studies suggest a predictable and more rapid osseointegration of implants with different surface treatments, e.g. blasted[10,11], acid etched[12,13], blasted plus acid etched[14–16], porous[17], oxidised[18] and titanium plasma sprayed[19,20]. A recent study has also questioned whether different surface treatments, besides changing the surface topography, perhaps even alter the surface chemistry, and thus also need to be considered as a variable in clinical studies[21].

Can the quality of dental implants be measured?

According to the International Organisation for Standardisation (ISO) a dental implant is: "*A device designed to be placed surgically within or on the mandibular or maxillary bone to provide resistance to displacement of a*

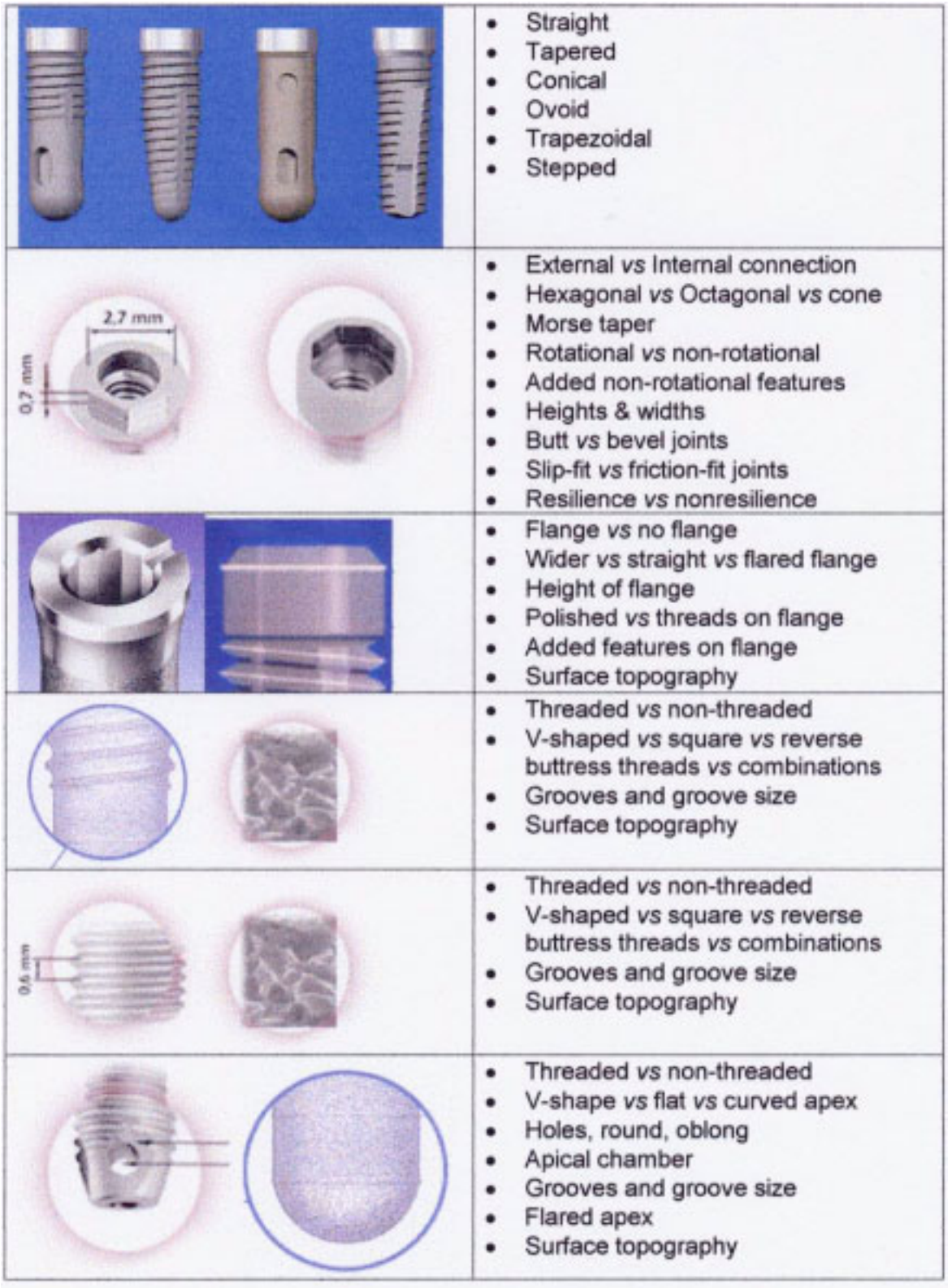

Figure 1. Variations in dental implant design features in general (top) and from top to bottom the implant/abutment interface, the implant flange, the coronal, the midbody and the apical thirds (bottom).

dental prosthesis" (ISO 1942-5). The corresponding definition for a dental implant system is: "*Dental implant components that are designed to mate together. It consists of the necessary parts and instruments to complete the implant body placement and abutment components"* (ISO 10451).

The definitions encompass two elements that may in theory be associated with aspects of quality. If the process that allows '*a device designed to be placed surgically*' for some implant systems is straightforward and not associated with high risk

Table 1 Methods used to alter surface topography of dental implants (sorted alphabetically).

Machining process	Resulting surface topography	Example
Acid etched surface (The surface is usually etched in a two-step procedure)	Isotropic surface with high frequency irregularities	HCl/ H_2SO_4 (Osseotite®, 3i Implant innovations, Palm Beach Gardens, USA)
Blasted surface (The surface is blasted with hard particles)	Creates an isotropic surface	TiO_2 particles (Tioblast®, Astra Tech AB, Mölndal, Sweden)
Blasted + acid etched surface (The surface is first blasted and then acid etched)	An isotropic surface	1. Large size Al_2O_3 particles & HCl & H_2SO_4 (SLA®, Institute Straumann AG, Waldenburg, Switzerland); 2. Tricalcium phosphate & HF & NO_3 (MTX®, Centerpulse Dental, Carlsbad, USA)
Hydroxyapatite coated surface	In general, a rather rough and isotropic surface	Sustain® (Lifecore Biomedical Inc, Chaska, USA)
Oxidized surface (Increased thickness of the oxidized layer)	Isotropic surface with the presence of craterous structures	TiUnite® (Nobel Biocare AB, Göteborg, Sweden)
Titanium Plasma Sprayed (TPS) surface	A relatively rough isotropic surface	ITI® TPS (Institute Straumann AG, Waldenburg, Switzerland)
Turned surface	Cutting marks produce an oriented, anisotropic surface	Brånemark System® MKIII (Nobel Biocare, Göteborg, Sweden)

of complications but not for other systems, this may be an indicator of quality. Evidently, simplicity of placement is in itself not an adequate criterion for implant quality, but must be regarded in context with material properties and other reported outcome criteria. The second element is '*providing resistance to displacement*'. Consequently, reliable documentation that this in fact is the case for a specific dental implant or implant system is a characteristic of high quality.

The ISO definition does not allude to any temporal requirements, but most people would probably agree that the '*resistance to displacement*' should remain for a minimum period, and preferably as long as possible. Thus, one direct estimate of the quality of a dental implant is the reported results observed in clinical trials that have lasted for an extended period, e.g. for more than five years. It should be required that the documentation of acceptable clinical performance are data obtained in a clinical trial with an appropriate research design and adequate level of external and internal validity.

The quality of a dental implant or implant system may also be defined by another dimension, which is the requirement that either the implant *per se* or the manufacturing process should conform to a national or an international standard. Although several countries demand that products need to comply with such standards in order to be marketed, this does not apply to all parts of the world. Moreover, the ethical conduct of the manufacturer is important, which is reflected by a sincere and exact format of the product documentation, as well as the form of the presentation of products, for the users, i.e. the dentist.

Scientific evidence and required study designs

Whether one wishes to address adequate clinical performance of an implant or whether the aim is to compare the performance of different products the choice of adequate scientific documentation will differ. The validity of any clinical trial, however, depends on an appropriate choice of outcome variables and reliable measurement of these, regardless of the study design. It is the authors' task to describe such details in their reports to enable the reader both to comprehend the paper but also, if wishing to do so, to repeat the trial without doubting how this was carried out.

Adequate clinical performance of an implant can best be demonstrated in a longitudinal trial, either prospective or retrospective. The external validity of such trials are to a large extent related to patient dropout and – representativity as well as other variables such as operator experience and clinical settings. One may also obtain an impression of clinical performance from reports of case series. However, there is an increased risk of selective recording of treatment data, as well as risk for spurious statistical associations. Moreover, potentially confounding variables are more or less difficult to account for and this may skew the treatment outcome without any chance of knowing by how much. The final type of clinical study type, case reports, often lack many details, which makes it difficult to interpret the implant performance in general.

Scientific documentation of superiority of one product versus another requires a more stringent study design. This is best appraised using a randomised controlled trial design (RCT). In a RCT the participants are allocated at random to receive different interventions. An appropriate random allocation means that all trial participants have the same chance of being assigned to either an experimental or to a

control group. Properly accomplished randomisation minimises systematic patient selection bias and since the groups thereby in theory become identical, apart from the intervention, any difference in outcome is attributable solely to the intervention. The larger the groups under study, the more confidence can be placed that it is the effect of the intervention that is reflected by the treatment outcomes and not some confounding underlying patient variables. It must be emphasised that a report based on a RCT does not automatically translate as a high quality paper. Critical appraisals of the literature in prosthodontics suggest that numerous RCTs are poorly reported[22,23].

If no RCTs can be identified for comparing products or specific implant characteristics, prospective controlled clinical trials, and to a lesser degree clinical trials using other study designs, provide some indications of product differences. However, the possibility of incorrect conclusions increases with these less stringent study designs due to risk of bias and influence of confounding variables. Studies that report the treatment outcome of a single patient cohort, prospectively or retrospectively, without any comparison group must not be used as the basis for comparisons of product performance. The reason is that variations between study variables such as clinical setting, clinician experience, treatment indication, patient selection and socio-demographics, etc. impede any meaningful comparisons because these significant variations can strongly influence the outcome.

Extrapolating laboratory study data to promulgate hardware claims and product superiority is invalid for generalising to the clinical setting since laboratory data, even if statistically significant, may be irrelevant or even directly misleading in the clinical environment. Only well-designed clinical trials can supply evidence of product differences that are clinically relevant.

The aim of this paper is to present and discuss the available scientific evidence of clinical performance of different dental implant systems. The objective is to help customers to recognise high quality dental implants on the basis of this evidence.

Materials and methods

Information presented by manufacturers

We first recorded as many manufacturers of dental implants and brands as possible by browsing dental journals and programme booklets for advertisements as well as lists of exhibitors at major implant and prosthodontic meetings. Languages were limited to English, German, Scandinavian, Spanish and French. We also appraised papers in dental journals and meeting abstracts for the same purpose. We identified thereafter the Internet websites of the manufactures. Next we appraised the websites and printed promotional material from the manufacturers to identify claims of product superi-

Table 2 Design characteristics of the dental implant that may be associated with clinical success. (Factors associated with inadequate quality control of the production process are excluded in this table, e.g. inferior materials, contamination and poor precision. These elements should be assured by the manufacturer's adherence to a production quality control standard, e.g. ISO9001)

Clinical outcome	Design characteristic
1. Ease of placement	• Implant body geometry
2. Osseointegration	• Implant body geometry • Implant material • Implant surface topography
3. Aesthetics	• Implant and abutment interface geometry • Abutment material and geometry
4. Peri-implant mucositis	• Implant body geometry • Implant material • Implant surface topography • Implant and abutment interface geometry • Abutment material, geometry and surface topography
5. Marginal bone loss	• Implant body geometry • Implant material • Implant surface topography • Implant and abutment interface geometry • Abutment material, geometry and surface topography
6. Mechanical problems of the implant/ abutment/ superstructure connections	• Implant body geometry • Implant and abutment interface geometry (Joint geometry strength, precision fit of components, torque reliability, i.e. clamping force) • Abutment material, geometry and surface topography
7. Mechanical failure of the dental implant	• Implant body geometry • Implant material • Implant dimensions

ority on the basis of one or more particular implant characteristics. We also recorded whether the manufacturer announced on their website or in their promotional material that either the manufacturing process or the implant conformed to any international standards, e.g. ISO, or if it is certified according to such standards, e.g. by a CEN notified body in Europe or FDA in USA. We contacted the manufacturers in several cases where no clinical studies of a specific implant brand could be identified, with an invitation to provide this information.

Claims of clinical superiority due to specific morphological characteristics could be categorised into seven general groups (*Table 2*).

Scientific literature

We systematically searched various electronic databases (Medline, Embase and the Cochrane Oral Health Group specialist register) to identify clinical trials on dental implants. We also hand-searched several implant journals in an attempt to reduce the likelihood of missing relevant articles. We also checked the bibliographies of studies and relevant review articles. Medline included, in October 2003, 6,353 articles indexed under 'Dental implant'. The Pubmed search using a methodology filter for sensitivity searching identified 574 papers on therapy and 1,345 on prognosis. The Cochrane Controlled Trials Register included 392 controlled clinical trials. The Finnish national register for dental implants, which includes data on placed and removed implants in Finland since 1994, was also used as a source to relate clinical performance to implant brand.

We identified all implants and implant systems that had been evaluated in the clinical trials. On the basis of the number of clinical trials and the scientific methodological quality of the reports we defined four levels of clinical documentation:

A. Implant or implant system with extensive clinical documentation, i.e. more than four prospective and/or retrospective clinical trials
B. Implant or implant system with limited clinical documentation, i.e. less than four trials, but of good methodological quality, i.e. randomised controlled trial or prospective clinical trial, either multicentre or with study samples consisting of more than 50 patients or 200 dental implants
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.

The next phase was to critically appraise the clinical trials that reported an association between clinical performance and specific characteristics of dental implants. In view of the high number of clinical studies, relatively few trials were designed to specifically evaluate the influence of specific characteristics of the implant (*Table 3*)[24–84] or the abutment (*Table 4*)[85–94] on clinical performance. We sorted the clinical trials according to the methodology strength of the study design. Four broad categories were defined:

- Category A1, clinically controlled trial with patient randomisation (RCT)
- Category A2, clinically controlled trial with split-mouth randomisation, (Split-mouth RCT)
- Category B, (prospective) clinically controlled trial without randomisation (CCT)
- Category C, clinical study applying any other study design than A or B (e.g. retrospective cohort, case-series, case-controls, etc.).

Results

We have, as at October 2003, identified about 80 manufacturers of dental implants, who market slightly more than 220 different implant brands (*Table 5*). In addition, approximately 60 implant brands/manufacturers were recorded, but these appear to have vanished from the market. However, it should not be ruled out that a small number of these may still be obtainable in various parts of the world.

About half of the manufacturers inform on their websites to what extent their company and products comply with an international standard or are certified (*Table 5*). Of these, it is almost universally a reference to ISO 9001 and/or EN 46001. Less common is a reference to the European Union medical device directive 93/42/EEC, to the CE notified body, to other ISO and EN standards or to a FDA market clearance or reference to the so-called FDA 510K. Most of the companies who do not present such information on their website have included this information in their printed promotional material, but some manufacturers still lack any information on this subject (*Table 5*).

Only a minority of the dental implant manufacturers can provide extensive clinical documentation of their implant brands for the patient (Code A in *Table 5*, n=10). In contrast, 29 manufacturers market dental implants with no clinical research documentation at all (Code D in *Table 5*).

A compilation of the different studies according to study designs and documented or appraised possible influences on treatment outcomes is presented in *Table 6*. Studies with lower levels of scientific evidence strength are only included in this review where there is a lack of studies with better study designs.

1. Ease of placement

Summary: Differences in ease of placement, as a function of the implant morphology have not been systematically evaluated in clinical trials. Two reported outcomes are operation time and surgeons' pref-

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]
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]
CS	Complex: Core Vent, Screw Vent® vs Swede Vent® vs Brånemark System®	85+11+105	>2	De Bruyn *et al.* 1992 (UK)[57]
CS	Complex: IMZ® vs ITI® Bonefit vs ITI® TPS	168+150+ 109	1–10	Gómez-Roman *et al.* 1998 (Germany)[58]
CS	Complex: Astra Tech Tioblast ® vs ITI® hollow screw	31+93	1–10	Ellegaard *et al.* 1997a, 1997b (Denmark)[59,60]

cont'd...

Study design*	Reported or appraised influence of implant characteristic on clinical performance	Sample (n)	Per. (yrs)	Authors
CS	Complex: ZL-Duraplant, Turned vs electrochemical surface & screw vs cylinder	58+369	3–5	Graf *et al.* 2002a, 2002b (Germany)[18,61]
CS	Complex: Astra Tech vs Brånemark System®	15x2	>2	Puchades-Roman *et al.* 2000 (UK)[62]
CS	Complex: Brånemark System® vs ITI®	90+32	1–8	Krausse *et al.* 2001 (Germany)[63]
CS	Complex: Brånemark System® vs Frialit®-2 vs IMZ®	1964	1–16	Noack *et al.* 2001 (Germany)[64]
CS	Complex: Brånemark System® vs IMZ®	384	1–8	Scurria *et al.* 1998 (USA)[65]
CS	Complex: IMZ® vs ITI® 3 implant geometries	264+36	0.5–11	Spiekerman *et al.* 1995 (Germany)[66]
CS	Complex: Brånemark System® screws vs IMZ® cylinders	54+133	2–	Valentini & Abensur 2003 (France)[67]
CS	Geometry: Brånemark System®, 4 screw geometries & 4 abutment geometries	252	1–8	Bianco *et al.* 2000 (Italy)[68]
CS	Geometry: ITI®, 4 implant geometries	2359	1–8	Buser *et al.* 1997 (Switzerland)[19]
CS	Geometry: ITI®, 5 implant geometries	654	1–7	Carr *et al.* 2003 (USA)[69]
CS	Geometry: Brånemark System®, 4 screw geometries & 4 abutment geometries	82	1–5	Engquist *et al.* 1995 (Sweden)[70]
CS	Geometry: ITI®, 4 implant geometries	1286	1–10	Ferrigno *et al.* 2002 (Italy)[71]
CS	Geometry: Brånemark System®, multiple screw & abutment geometries	1141	1–10	Lentke *et al.* 2003 (Germany)[72]
CS	Geometry: Brånemark System®, 3 screw geometries & 2 abutment geometries	84	1–6	Malevez *et al.* 1996 (Belgium)[73]
CS	Geometry: Brånemark System®, 5 screw geometries	270	1–11	Naert *et al.* 2000 (Belgium)[74]
CS	Geometry: Brånemark System®, 3 screw geometries	668	1–15	Naert *et al.* 2001 (Belgium)[75]
CS	Geometry: Brånemark System®, 5 screw geometries & 4 abutment geometries	1956	1–16	Naert *et al.* 2002a, 2002b (Belgium)[76,77]
CS	Geometry: Brånemark System®, 3 screw geometries	1279	1–3	Quirynen *et al.* 1992 (Belgium)[78]
CS	Geometry: Brånemark System®, standard & MKII screws	84+86	3	Raghoebar *et al.* 2003 (International)[79]
CS	Geometry: ITI®, 2 implant geometries	187	1–7	Romeo *et al.* 2002 (Italy)[80]
CS	Geometry: Frialit®-2, stepped screw vs stepped cylinder	802	1–5	Wheeler 2003 (USA)[81]
CS	Material: Bicon®, HA vs Ti vs TPS	2349	0–7.5	Chuang *et al.* 2002 (USA)[82]
CS	Material: not specified, HA vs Ti	2098	1–6	Weyant & Burt 1993 (USA)[83]
CS	Surface: 3i, Dual-etch vs turned vs self-tapping vs ICE® vs Osseotite®	1583	1–5	Davarpanah *et al.* 2002 (France)[84]

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

erence. One split-mouth RCT focused on influence of geometry and suggested a slight effect on primary stability, albeit operator bias cannot be avoided. There are no studies with specific focus on influence of implant material or s urface topography. Implants with different geometry, material and surface topography have been evaluated in two RCTs and one split-mouth RCT. These present 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. One clinically controlled trial with focus on influence of geometry has also suggested that 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.

Category A1 studies: Randomised controlled trials

Studies where implant geometry, material and surface topography influences on the outcome 'ease of placement' are confounded.

The time for surgical installation of Brånemark system® implants in the mandible has been measured to be 65 minutes and 77 minutes for ITI®

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

Table 5 List of manufacturers and implant brands. Documentation of clinical and laboratory studies can be found in a database with links to manufacturers' websites located on the website of the FDI World Dental Federation (http://www.fdiworldental.org/resources/implants.htm). Validation codes: A: Extensive clinical documentation; B: Some documentation identified of acceptable quality; C: Some documentation identified, but of poor quality; D: No clinical documentation

Manufacturer, Country	Implant brands	Document	Information on website	Comply to standard, as registered elsewhere
1. 'O' Company Inc., USA	1. Cylinder 2. Threaded 3. Performance Plus Taper 4. RBM Blade	D	–	FDA
2. 3i Implant Innovations, Inc., USA	5. ICE Super Self-Tapping 6. Osseotite® TG™ 7. Osseotite® 8. Osseotite® XP™ 9. Osseotite® NT™ 10. Osseotite® Certain™	A	–	ISO9001, EN46001, (CE0483), FDA
3. ACE Surgical Supply Comp, USA	11. Ace screw (Ace Dental Implant System)	C	ISO9001, EN46001	
4. Alpha Bio GmbH, Germany	12. DFI (Dual-Fit-Implant)	D	(CE0483)	
5. Altatec Medizintechnische Elemente GmbH & Co. KG, Germany	CAMLOG® implant system 13. Cylinder Line 14. Root Line 15. Screw Line 16. Screw-Cylinder Line	B	–	ISO5832&5833 ISO13484, EN46001, (CE0124)
6. Altiva Corp., USA	17. NTR Natural Tooth Replacement System™	C	FDA market clearance	FDA
7. Anthogyr, France	18. Hexagon System 19. Octagon System 20. Temporary	B	ISO9001, EN46001	
8. AS Technology, Brazil	21. Titanium Fix Auto Rosqueável Hex 22. Roscado Hex23. Roscado Hex PS	D	–	–

cont'd...

Manufacturer, Country	Implant brands	Document	Information on website	Comply to standard, as registered elsewhere
9. Astra Tech, Sweden	24. AstraTech 25. AstraTech ST 26. Fixture MicroThread™	A	ISO9001/ISO14001	EN46001, CE, FDA
10. Basic Dental Implants LLC, USA	27. Omni-Tight™	D	–	FDA
11. BEGO Semados, Germany	28. Semados®	C	–	CE 0044, DIN ISO9001 + 9002, EN 46001
12. Bicon Dental Implants, USA	29. Bicon Implant System	B	–	ISO9001, EN46001, CE, FDA
13. BioHorizons Implant Systems, Inc, USA	30. Maestro™ System	B	–	ISO9001, EN46001, CE, FDA
14. Bio-Lok International, Inc. (Subsid.: Orthogen Corp.), USA	31. Classic Cylinder 32. LaserLok™ 33. Micro-Lok™ Screw 34. Micro-Lok™ Cylinder 35. Silhouette™ 36. Silhouette™ I.C.	D	ISO9001, (CE0123) FDA 510K	ISO9001, EN46001, CE, FDA
15. BioHex Corp. (prev. Biomedical Implant Technology), Canada	37. BioHex™ (prev. BIT™) One Piece-One Stage™ Implant System	C	HPB (Canada), FDA regulations	FDA
16. Biotechnology Institute, S.L., Spain	38. B.T.I. Implant	C	ISO9001, EN46001, MDD93/42/EEC (CE0123)	
17. Bone System, Italia	39. Bone System 2	D	ISO9001, EN46001, MDD93/42/EEC (CE0123)	
18. BTLock s.r.l., Italia	BTLock System 40. Screw: turned, acid-etched, HA coated, TPS coated, BTTITE 41. Cylinder: Screw: turned, acid-etched, HA coated, TPS coated, BTTITE	D	ISO9001, EN46001, MDD93/42/EEC (CE0373)	
19. Centerpulse Dental Inc. (prev. Sulzer Dental) (prev. Calcitek), USA	42. Taper Lock 43. Swiss-Plus 44. Swiss-Plus +taper 45. Screw-Vent® 46. Screw-Vent® +taper 47. AdVent 48. Spline	A	ISO9001	ISO9001, EN46001, CE, FDA
20. Cowell Medi , Korea	49. Bioplant External Type 50. Bioplant Internal Type	D	–	–
21. Cresco Ti Systems, Switzerland	51. OI-90 Implant Series (Osseo-Integrator)	C	ISO9001, EN46001	
22. Dental Tech, Italy	52. Physioplant dental implant system	D	–	ISO9001, EN46001
23. Dentatus, Sweden	53. MTI-Monorail™ Transitional	A	–	
24. Dentoflex Comércio e Indústria de Materiais Odontológicos, Brazil	54. Dentoflex de hexágonos externo 55. Dentoflex de hexágonos interno	D	–	–
25. Dentsply Friadent, Germany	56. ANKYLOS implant system 57. FRIALIT®-2 stepped cylinder, HA 58. FRIALIT®-2 -stepped screw, TPS 59. FRIALIT®-2 -stepped screw Synchro, TPS 60. FRIALIT®-2 -stepped screw, Tiefstruktur 61. FRIALIT®-2 -stepped screw, Synchro Tiefstruktur 62. XiVE® 63. XiVE®TG 64. IMZ®-TwinPlus implant system 65. Friadent® CELLplus	A	(CE0123)	ISO9001, EN46001, FDA

cont'd...

Manufacturer, Country	Implant brands	Document	Information on website	Comply to standard, as registered elsewhere
26. Dr Ihde Dental GmbH, Germany	Allfit ® 66. ATI 67. ATIE 68. Compression 69. DiskosEDDDS/EXDDS 70. Diskos EDXAAS 71. KOS 72. SSO 73. STC 74. STI 75. STO	C	–	(CE0483)
27. Dyna Dental Engineering b.v., Netherlands	76. Dyna Octalock®	C	–	ISO CE
28. Eckermann Laboratorium, Spain	77. Eckermann Plus! 78. Eckermann Transicional 79. Eckermann Duplo 80. Eckermann All Spiral	C	ISO13485, (CE0318)	
29. Elite Medica, Italy	81. Elite Implant System 82. Fastite 83. Mini	C	ISO9001, EN46001	
30. Euroteknika, France	84. Secure	D	–	
31. Impladent Ltd, USA	85. LaminOss® Osteocompressive Implant System	C	–	ISO9001, EN46001, CE, FDA
32. Impladent S.L, Spain	86. Defcon®	D	–	–
33. Implant Microdent System, S.L, Spain	Microdent System 87. Microdent Universal 88. Especial Serie MS-Micro 89. Especial Serie MT	D	–	(CE0318)
34. IMTEC Corporation, USA	90. Press-Fit 91. Press-Fit TPS 92. Screw-Type 93. Sendax MDI	B/C	ISO9001, EN46001, Œ	FDA
35. Innova LifeSciences Corp, Canada	94. Endopore™ 95. Entegra™	A	ISO9002, CE, FDA 510K	ISO9002, EN46002, CE, FDA
36. Institut Straumann AG, Switzerland	ITI® Dental Implant system 96. Screw 97. Screw Esthetic Plus 98. Hollow Cylinder 99. Hollow Cylinder, Esthetic Plus 100. ITI® Narrow Neck (NNI) 101. ITI® Wide Neck (WNI) 102. ITI® TE™	A	ISO9001, EN46001, (CE0123)	ISO9001, EN46001, CE, FDA
37. Interdental S.R.L, Italia	Ergo-System 103. External Exagon 104. Internal Exagon	C	ISO9001, EN46001, (CE0546)	
38. Jmp dental GmbH, Germany	105. jmp Mini-Implantat	D	–	–
39. JOTA AG, Switzerland	106. JOTA	D	ISO9001, EN46001, (CE0408)	
40. Klockner Implants, Spain	Klockner system 107. K2 108. SK4 109. S3 110. S4 111. S6	B	ISO9001, EN46001, (CE0318), FDA	
41. LASAK Ltd, Czechia	112. Impladent	B	ISO9002 EN46002	
42. Leone S.p.A, Italy	113. Leone Implant System	D	ISO9001 EN46001 ISO13485	

cont'd...

Manufacturer, Country	Implant brands	Document	Information on website	Comply to standard, as registered elsewhere
43. Lifecore Biomedical, Inc., USA	114. Restore, Threaded, RBM, regular&wide 115. Restore, Threaded, TPS, regular&wide 116. Restore, Threaded, Ti, regular&wide 117. Restore, Threaded, HA, regular&wide 118. Restore, Cylinder, RBM, regular&wide 119. Restore, Cylinder, TPS, regular&wide 120. Restore, Cylinder, Ti, regular&wide 121. Restore, Cylinder, HA, regular&wide 122. Stage-1™, RBM, regular&Wide, +/-Esthetic Collar 123. Stage-1™, TPS, regular&Wide, +/-Esthetic Collar 124. SuperCAT Super Self-Tapping 125. Sustain, HA coated (MC) cylinder	A	ISO9001, EN46001, FDA	
44. MIS Implant Technologies Ltd Company (MIS), Israel	MIS Trio Implant System 126. Internal connection 127. External connectionMIS implants 128. Bio-Com Fixture 129. Internal hexagon, Screw 130. Internal hexagon, Cylinder 131. External hexagon, Screw 132. External hexagon, Cylinder	C	–	EN 46001, ISO9001, FDA
45. Mozo-Grau, Spain	133. Mozo-Grau Threaded 134. Mozo-Grau Cylinder	C	–	(CE 0044), EN 46001, ISO9001, FDA
46. Neobiotech Comp. Ltd. Korea	135. Neoplant Fixture Surface treated 136. Neoplant Ficture Turned Surface	D	–	–
47. Neodent, Brazil	137. Titamax Liso I 138. Titamax Liso II 139. Titamax Poros 140. Titamax Dual	D	–	–
48. Nobel Biocare, Sweden	141. Brånemark System® MKIII, 142. Brånemark System® MKIII, TiUnite 143. Brånemark System® MKIV, 144. Brånemark System® MKIV, TiUnite 145. Replace® Select, Straight, NP, RP, WP 146. Replace® Select, Tapered, NP, RP, WP 147. Replace® Select, Straight, NP, RP, WP, TiUnite 148. Replace® Select, Tapered, NP, RP, WP, TiUnite 149. Replace® Select, Straight, NP, RP, WP, HA 150. Replace® Select, Tapered, NP, RP, WP, HA 151. NobelPerfect™	A	ISO14001	ISO9001, EN46001, CE, FDA
49. Odontit S.A. Argentina	152. Implante eFeDeA™ 153. Implante Osseomate™	D	–	FDA
50. Oral implant S.R.L, Italy	154. Tramonte Screw	D	–	–
51. Oraltronics, Germany	155. Pitt-Easy®Bio-Oss 156. Bicortical® Screw I 157. Osteoplate®2000	C	ISO9001, EN46001, FDA	
52. Osfix Intl Ltd, Finland	158. BiOsfix	C	(CE0537)	
53. Osstem Comp. Ltd, Korea	159. Avana System	C	ISO9001, (CE0434)	
54. Osteo-Implant Corp., USA	160. Osteo® Threaded 161. Osteo® HA	C	ISO9001	FDA
55. Osteo-Ti, UK	162. Osteo-Ti implant system	C	Œ	
56. PACE™ Dental Technologies, Inc., USA	163. PACE™	D	FDA 510K	
57. Paraplant 2000, Germany	164. Paraplant 2000	D	–	–

cont'd...

Manufacturer, Country	Implant brands	Document	Information on website	Comply to standard, as registered elsewhere
58. Park Dental Research Corp., USA	165. Star*Lock™ Screw, RBM, 166. Star*Lock™ Screw, TPS 167. Star*Lock™ Screw, HA 168. Star*Lock™ Cylinder, RBM, 169. Star*Lock™ Cylinder, TPS 170. Star*Lock™ Cylinder, HA 171. Star/vent™ Screw, RBM, 172. Star/vent™ Screw, TPS 173. Star/vent™ Screw, HA 174. Star/vent™ Cylinder (Press-fit), RBM, 175. Star/vent™ Cylinder, TPS 176. Star/vent™ Cylinder, HA 177. Startanius Blade	C	ISO9001, (CE0459)	
59. Pedrazzini Dental Technologie, Germany	178. press quick®	D	(CE0301)	
60. RT Medical Research & Technologies, Italy	179. Inner Hexagon Line, Post-extractive 180. Inner Hexagon Line, Standard 181. Outer Hexagon Line, Post-extractive 182. Outer Hexagon Line, Standard	D	ISO9001, EN46001, (CE0476)	
61. Sargon Enterprises Inc, USA	183. Sargon® Immediate Load™	B	ISO9001, EN46001, (CE0470)	FDA
62. Schrauben-Implantat-Systeme GmbH, Germany	184. K.S.I.-Bauer-Schraube	C	–	(CE0482)
63. Schütz-Dental, Germany	185. IMPLA smart	D	–	ISO9001, CE
64. SERF (Société d'Etudes, de Recherches et de Fabrications), France	186. EVL	C	ISO9002, (CE0413)	
65. Simpler Implants Inc., Canada	187. Simpler (HA) 188. Simpler Threaded 189. Simpler1 (HA) 190. Simpler1 Threaded	C	ISO9002, CE, FDA, DHW	
66. Southern Implants (Pty) Ltd, South Africa	191. External Hexed 192. Internal Hexed	B	(CE0124)	
67. Star-Group-International GmbH, Germany	193. Sky-Implant-System	D	–	–
68. Sterngold Implamed® Dental Implant Systems, USA	194. Implamed Turned, TPS, Regular, Wide & Narrow 195. Implamed Turned Partial TPS, Regular, Wide & Narrow 196. Implamed Turned Regular, Wide & Narrow 197. Implamed HA, Regular, Wide & Narrow 198. ERA Implant System	A	ISO9001, EN46001, (CE 0197), FDA	FDA
69. Sudimplant, France	T.B.R.® system 199. Oct-In 200. Hex-out 201. Z-1	C	ISO9002, EN46002	(CE0459)
70. Sweden & Martina SpA, Italy	202. Pilot® 203. Premium® standard 204. Premium® conical 205. Premium® Trisurface 206. Premium® Kohno 207. Premium® Aurum 208. Premium® cylindrical 209. PRO-Link® Out-Link® 210. PRO-Link® In-Link®	C	–	(CE0476) ISO9002, EN46002
71. Tenax Dental Implant Systems, Canada	211. Tenax Dental Implant System	C	Clearance in Canada only	
72. TFI System, Italia	Easy Grip® 212. Short neck 213. Wide 214. Bullet, TPS 215. Large	C	ISO9001, EN46001, (CE 0476)	

cont'd...

Manufacturer, Country	Implant brands	Document	Information on website	Comply to standard, as registered elsewhere
73. Thommen Medical, Switzerland	216. SPI®Element 217. SPI®Direct 218. SPI®Onetime	D	ISO9001, EN46001, MDD93/42/EEC	
74. Timplant, Czechia	219. Timplant®	D	ISO9002, EN46002	
75. Tiolox implants GmbH, Germany	220. Tiolox 221. Tiolox HA	C	–	(CE0483)
76. Trinon Titanium GmbH, Germany	222. Q-Implant® 223. jmp Mini-implant no. 1	C	ISO9001, EN46001, (CE0483)	
77. Victory-med, Germany	224. Disk-implantate	B	–	
78. ZL-Microdent-Attachment GmbH, Germany	225. ZL-Duraplant	B	(CE0044)	ISO9001 EN46001

* FDA: FDA Quality System Regulation (formerly GMP, Good Manufacturing Practice)

Table 6 References of the identified clinical studies where clinical outcomes have been associated with implant or implant abutment characteristics, identified as Geometry -, Material -, Surface topography or combinations of these (Complex). A1: RCT: Randomised controlled trial, A2: Split-RCT: Split mouth randomised controlled trial, B: Controlled clinical trial, C: clinical study applying any other study design than A or B (e.g. retrospective cohort, case-series, case-controls, etc.)

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]	–

hollow screw implants ($p < 0.05$)[29]. The authors proposed that extra time for the ITI® implants (n=106) was needed to select proper healing caps and careful suturing. The additional time needed for the abutment connection in a second stage surgery on the Brånemark system® implants (n=102) took on average 42 minutes. The authors reported on the other hand that the time needed for the following prosthodontic procedures and subsequent controls favoured the Brånemark system®. Thus, it was suggested that in sum, the total accumulated time needed for a complete treatment did not differ between the two systems.

The time used for surgically inserting Astra Tech Tioblast® implants (n=184) and Brånemark system® MKII implants (n=184) in 66 patients was reported by

Åstrand *et al.*[27]. The surgery operation time did not differ, i.e. 89 minutes in the mandible and 95 (Brånemark) and 102 (Astra Tech) minutes in the maxilla. Attaching the abutments at the second surgery stage was found to be more time consuming for the Brånemark system® implants, i.e. 51 minutes and 43 minutes versus 35 minutes and 32 for the Astra implants in the maxilla and in the mandible ($p<0.05$).

Category A2 studies: Split-mouth randomised design, or random initially with alternate subsequent placement

Implant geometry influence on the outcome 'ease of placement'.

Friberg *et al.*[45] compared the early behaviour of a Brånemark system® modified prototype MKIV implant with that of the standard implants in regions of mainly type 4 bone in 44 patients. The patients were treated with implants for 39 maxillas and 5 mandibles and these were followed up for 1 year. The MKIV implants more frequently required a higher insertion torque and showed a significantly higher primary stability than the control implant. This difference in stability levelled out over time, at the abutment operation and at the 1-year visit the stability was similar.

Studies where implant geometry, material and surface topography influences on the outcome 'ease of placement' are confounded.

The average time used for surgically placing Astra Tech Tioblast® implants (n=50) and Brånemark system® MKII implants (n=45) in 18 patients did not differ between the two systems regarding implant surgery, i.e. 42 minutes[44]. The abutment connection was reported to be faster on the Astra Tech implants (15 min *vs.* 20 min). The authors experienced difficulties in obtaining a clinically acceptable fit between the Astra Tech abutment and the superstructure and attributed this to the conical shape of the abutment and complication in obtaining perfect alignment.

Category B studies: Clinically controlled trials

Implant geometry influence on the outcome 'ease of placement'.

Friberg *et al.*[54] compared the simplifying of the surgical insertion technique by modifications of the screw geometry. Brånemark system® self-tapping (MKII) and standard implants (n=179) were compared. The authors had intended to carry out the study as a prospective split-mouth RCT, but this was abandoned while the study progressed. The new implant geometry was not entirely successful, in that certain problems were encountered during the surgical insertion. The implant geometry was therefore modified and evaluated in a subsequent trial on 563 implants in 103 patients. After the motor driven equipment used to install the implants had been modified a slight improvement was obtained with the new screw geometry [55,56].

2.Osseointegration

Summary: 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. 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. Implants with different geometry, material and surface topographies have been evaluated in six RCTs and three split-mouth RCTs. These studies fail to demonstrate clear differences between different implant brands regarding osseointegration. This was also corroborated in 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. Finally, 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 recognised.

Category A1 studies: Randomised controlled trials

I*mplant geometry influence on the outcome 'osseointegration'.*

Pairs of cylinder IMZ® with TPS coating or ITI® solid screw implants with TPS coating were placed in the mandibles of 40 patients with moderate jaw resorption and overdentures retained by bar and clip attachments were made after three months. Results after one[32] and two years[31] have been presented. Only one IMZ® implant was lost, negating any meaningful inferences about comparability. The implant coatings are assumed to be identical, but the correctness of this is uncertain. Moreover, the confounding by other clinical variables makes it difficult to draw any strong inferences on the (lack of) influence of implant geometry on osseointegration.

Implant material influence on the outcome 'osseointegration'.

IMZ® implants with hydroxyapa-

tite (HA) or titanium plasma-flame (TPF) were compared over 3–7 years by Mau *et al.*[36]. TPF can be considered as synonymous to titanium plasma spray, TPS. The study sample consisted initially of 313 patients with partially edentulous mandibles treated in five German clinical centres. Due to early drop-outs, implant failures, protocol violations or patient non-compliance the study reported the outcomes of 89 patients assigned to receive HA and 100 patient receiving TPF implants. One implant was placed in each patient that supported a combined tooth-implant fixed bridge. The employed outcome criteria were implant loss, significant bone loss, periotest values and manual mobility of the tooth or implant. The investigators used multivariate log-rank test on the survival data. Moreover, separate analyses were conducted for the participants who switched from the assigned treatment according to the intention-to-treat principle, as well as sensitivity analyses using best and worst case scenarios for these patients. No differences were noted between the two surfaces regarding osseointegration, nor any of the other outcome criteria addressed in this trial.

Titanium plasma-sprayed cylinder implants (Sterngold-Implamed®) with and without additional hydroxyapatite coatings were compared by Jones *et al.*[34]. The study involved 65 patients who received 352 implants in different intra-oral sites to retain a variety of single crowns, overdentures and fixed bridges. The authors suggested that the HA coated implants allowed a better initial osseointegration, but a subsequent paper reported no differences between the two implant systems following five years of observation[35]. This report was difficult to critically appraise as there seemed to be several confounding variables influencing the result, lack of study detail descriptions and no other outcomes besides 'loss of implant' were reported. Both the internal and external validity of this study can therefore be questioned.

Implant surface topography influence on the outcome 'osseointegration'.

TiUnite (n=66) and turned Brånemark system® (n=55) implants in the posterior mandibles in 44 patients following applying immediate loading of partial fixed bridges were compared for one year by Rocci *et al.*[37]. All fixed two- to four-unit bridges were connected on the day of implant insertion. The cumulative success rates were 85 per cent for the turned (8 failed) and 97 per cent for theTiUnite (3 failed) after one year of prosthetic load in the posterior mandible. The authors attributed the relatively high failure rates to smoking and poor bone (quality 4) sites.

Studies where implant geometry, material and surface topography influences on the outcome 'osseointegration' are confounded.

Meijer *et al.*[28] presented five-year data of edentulous patients fitted with a mandibular overdenture either retained by two IMZ® (29 patients) or two Brånemark system® (n=32) implants. Four implants were lost in the IMZ® group (93 per cent survival), while for the Brånemark system® implants the survival rate was 86 per cent (9 implants lost). The difference was reported to be not statistically significant.

Southern and Sterioss implants were compared by Tawse-Smith *et al.*[16,30]. The implants were loaded after 12 weeks[16], or after 6 and 12 weeks[30] when a mandibular overdenture was provided for the patient. No differences were noted in the first study that included 24 patients[16]. In the second study 48 patients were allocated to four groups of 12 patients, each receiving the two implants after 6 weeks or 12 weeks. The Sterioss implants were on average shorter than the Southern. Better performance regarding osseointegration was demonstrated for the Southern compared to the Sterioss implants, of which eight failed to osseointegrate. Seven of these had been loaded after six weeks, they were in average shorter than the other implants in this study and they had all been inserted by one of the three surgeons involved in the study. Thus, it is unclear whether the lack of osseointegration of these Sterioss implants could be coincidental, whether it depended on differences in roughness, length or implant geometry or on the fact that the same surgeon had placed them all.

Brånemark system® implants (n=102) and ITI® hollow screw implants (n=106) placed in the mandible were compared in 40 edentulous patients by Moberg *et al.*[29]. Each patient received four, five or six implants to retain a fixed bridge. Only one implant failed to osseointegrate (Brånemark system®), thus no statistical difference was demonstrated.

Brånemark system® MKII (n=187) and Astra Tech Tioblast® (n=184) implants placed in different intra-oral regions in 66 patients were evaluated over one year by Åstrand *et al.*[26]. Eight Brånemark system® and one Astra Tech implant failed to osseointegrate, which is a statistically significant difference on implant level ($p<0.05$). Five of the Brånemark system® implants that failed to osseointegrate occurred in one patient, so no difference was noted when using the patient as the unit for statistical comparison.

Pairs of hollow screw ITI®, Brånemark system® and IMZ® implants were evaluated in three groups of 30 patients with extensive bone loss in the mandible[24]. During the post-surgery healing period, 1/60 Brånemark system® and 1/60 IMZ® implants failed to osseointegrate. The high clinical success rates in relation to a relative small study sample negate any meaningful inference of statistical significance.

Single tooth implants made from Astra Tech (n=46) or ITI® hollow screw and hollow cylinder (n=56) implants in different intra-oral

regions of 82 patients were evaluated by Kemppainen *et al.*[27]. Only one implant failed to osseointegrate (Astra Tech), so no statistical difference was demonstrated.

Category A2 studies: Split-mouth randomised design

Implant geometry influence on the outcome 'osseointegration'.

Friberg *et al.*[45] compared the early behaviour of a modified prototype Brånemark system® MKIV implant with that of the standard implant in regions of mainly type 4 bone in 44 patients. The patients were followed up for one year and the one-year cumulative success rate was 93 per cent for the MKIV versus 88 per cent for the conventional implants (no statistically significant difference).

Implant surface topography influence on the outcome 'osseointegration'.

Turned (n=185) and acid-etched (n=247) implants of the same geometry manufactured by 3i placed in 97 completely or partially edentulous patients by several operators at two clinics was reported by Khang *et al.*[48]. Criteria for success were the absence of peri-implant radiolucency, mobility, and persistent signs or symptoms of pain or infection. The implant lengths and diameters varied, as did the proportion of implants in anterior and posterior maxilla and mandible. The survival statistics were therefore analysed with general modelling estimations, i.e. multivariate analyses. The implant surface was identified as a significant factor for the development of osseointegration. Of the initially 432 implants a higher proportion of the etched implants osseointegrated versus the turned ones (95 per cent *vs* 87 per cent). The difference was maintained throughout the observation period following the loading of the implants. Several perplexing details are reported. One is that the time between surgical placement and loading was in average 12.7 months. Moreover, the temporal descriptors of the various phases of the trial do not add up correctly. Finally, in spite of a reported random allocation of the implant, marked asymmetries of intraoral location were noted. No details were provided regarding how the general estimation equations and Kaplan-Meier analyses were carried out and nor patient drop-out or proportion of censored data were presented. Thus, the inadequate reporting cast doubt about the general validity of this study.

Sandblasted and acid-etched (SLA) (n=68) and titanium-plasma spray (TPS) (n=68) ITI® implants of the same geometry were evaluated in a double blind study by Roccuzzo *et al.*[14]. The implants were placed in posterior regions of the mandible. No implant losses were reported during the healing stage and at one-year follow-up. Thus, the two surfaces seemed to be comparable when addressing the initial osseointegration, at least for this implant geometry over a short-term period. It should be noted that in this trial the SLA implants were loaded at 43 days postsurgically, while the TPS implants were loaded after 86 days.

Turned versus TiO_2-blasted Astra Tech implants were evaluated in a multicentre clinical study by Karlsson *et al.*[47]. Fifty patients received at least one turned and one TiO_2 -blasted implant to support fixed bridges in various locations in both jaws. Only two implants, both turned, out of initially 129 failed to osseointegrate. Thus, no difference with respect to initial osseointegration could be demonstrated. However, relating the very high clinical success rates in context with the relatively small study sample precludes meaningful generalised conclusions.

Studies where implant geometry, material and surface topography influences on the outcome 'osseointegration' are confounded.

Åstrand *et al.*[38] compared the outcome of fitting fixed partial bridges in the maxilla of 28 patients supported one side by ITI® and on the other side by Brånemark system® implants. The healing period was six months for both systems to allow for a single- versus two-stage surgery technique and the observation time was one year after loading. No significant difference in survival rate was noted with two Brånemark system® implants (in one patient) and one ITI® implant lost.

Astra Tech Tioblast® (n=50) and Brånemark system® MKII (n=45) implants placed in 18 patients were compared by van Steenberghe *et al.*[44]. One implant was reported lost (Brånemark system®), presumably due to lack of osseointegration. The very high clinical success rates in relation to a relative small study sample negate any meaningful inference of statistical significance.

One group of investigators included in their study nearly 3,000 screws, straight and grooved cylinder and hollow cylinder implants made from pure titanium and titanium alloys with and without HA-coating. The sponsor of the study had manufactured all the implants (Spectra-Vent). Pairs of different implants were allocated on a split-mouth basis and stratified by different intra-oral locations. Added to the complexity of the study design are difficulties in interpreting the long-term findings as the results are not presented according to the original stratification and implant allocation plan. Finally, the reported numbers of placed implants vary in the different study reports, e.g. n=1,565[41], n=2,910[42] and n=2,641[43]. In spite of the many methodological issues that can be raised, however, a common denominator in the many reports from this study material is that for the Spectra system implants, the HA-coated implants and the titanium implants were comparable regarding osseointegration.

Category B studies: Clinically controlled trials

Studies where implant geometry, material and surface topography influences on the outcome 'osseointegration' are confounded.

Chiapasco & Gatti[50] evaluated 328

implants placed in the interforamen area of edentulous mandibles and immediately loaded with an implant-supported overdenture. Four implant systems were used, Ha-Ti® (n=164), ITI® (n=84), and 40 each of Brånemark Conical® and Frialoc implants. Four implants were placed per patient. Failure criteria were absence of clinical mobility, peri-implant radiolucency, pain and peri-implant bone resorption less than 0.2mm after the first year of prosthetic load. The success rates after three years were 98 per cent for Ha-Ti®, and 95 per cent for the three other systems. Eight year survival estimates were only available for Ha-Ti® (89 per cent) and ITI® (90 per cent), i.e. no differences between the systems were noted.

Pinholt[51] compared ITI® and Brånemark system® implants placed in augmented extremely atrophic maxilla in 25 patients; 78 Brånemark® and 80 ITI® SLA implants were inserted in the augmented bone and the patients were followed between 20 and 67 months post implantation. The survival rates were 81 per cent for the Brånemark® (15 losses) and 98 per cent for the ITI® fixtures (2 losses) but the author failed to describe at what time this survival estimate is calculated. The results of this evaluation show that sandblasted large grit acid etched surface-treated ITI® implants has a significant higher survival rate than turned Brånemark® implants in autogenous grafted maxillary bone.

ITI® titanium-plasma spray (TPS) and Brånemark system® implants were compared in a multicentre trial by Becker *et al.*[49]. Three different surgeries each treated 29 patients using their own surgical techniques, i.e. one stage surgery for ITI® implants (n=78), and one stage (n=80) and two-stage (n=78) protocols for Brånemark system® implants. Failed osseointegration occurred for two ITI®, three two-stage Brånemark system®, and two one-stage Brånemark system® implants. The study design with three separate patient samples and the low incidence of osseointegration failure in relation to a relative small study sample negates any meaningful inference of statistical significance.

Category C studies: Clinical studies with other study designs

Many of the studies in this category do not present enough details to establish whether the numbers represent failure to develop osseointegration (i.e. early failure) or established osseointegration that subsequently failed (i.e. late failure). The last category includes reports that use criteria such as 'exfoliated implants', 'implant mobility', 'implant loss', 'implant removal' etc, which can only be presumed to indicate progressive loss of osseointegration.

Implant geometry influence on the outcome 'osseointegration'.

Wheeler[81] reported the results of the use of the 802 Frialit®-2 System implants in a private practice setting. Both threaded and press-fit forms had been used with comparable survival rates (95 per cent *vs* 97 per cent). The author reported that his experience was that the use of stepped cylindrical Frialit®-2 implants should not be used in immediate extraction situations.

Hollow screw and solid screw implants manufactured by ITI® (n=178) placed in 109 partially edentulous patients were compared by Romeo *et al.*[80]. A retrospective study based on observation times between one and seven years indicated that the hollow screw and solid screw demonstrated fairly similar success rates (95 per cent *vs* 93 per cent after five years). This corroborates earlier findings reported by Buser *et al.*[19]. These latter authors also reported significantly better performance for screw (n=1780) versus (hollow) cylinder (n=336) implants (96 per cent *vs* 91 per cent at 7 years). This conclusion was based on a multicentre study with observation times between one and eight years of 2,359 implants placed in 1,003 patients. The manufacturer discontinued the production of ITI® hollow screws in 1997, not because of any clinically dramatic results but rather due to risk estimation taking into account the inability of access for therapy in case of infection in the bone internal to the implant.

Brånemark system® implants have since their introduction had slightly different geometries. Investigators in Leuven, Belgium have published several papers that describe their clinical experiences using the different implants and associations to different clinical outcomes[74–78]. Early studies indicated better outcomes when using self-tapping implants versus earlier types. Inferior results were obtained with a conical type implant introduced by Nobelpharma in 1987, which was withdrawn a few years later because of poor clinical performance. Recent papers, including the patient sample pools of the earlier reports, report no differences in performance as an influence of the different geometries of the Brånemark system® implants[74–77].

Implant material influence on the outcome 'osseointegration'.

Chuang *et al.*[82] carried out a retrospective analysis of 2,349 implants in 677 patients to identify risk factors associated with failures of Bicon implants. An adjusted multivariate regression model was used that took into account clustering effect of implant failures within the same subject. Implant failures were not associated with coating (HA, TPS or turned).

Weyant and Burt[83] presented survival probabilities of 2,098 implants placed in 598 patients in multiple US Veterans dental clinics. Statistical modelling analyses identified no differences regarding osseointegration between HA coated and titanium implants. The study fails to mention which implant brands had been used, making it difficult to generalise the results to commercial products.

Implant surface topography influence on the outcome 'osseointegration'.

The complexity of the relationship between surface treatment of titanium implants and long-term clinical performance is noticeable in a case-series report presented by Davarpanah *et al.*[84]. Patients at 13 European centres had over a 1–5 years period received turned self-tapping (n=419), ICE (n=619) and Osseotite® (n=545) implants. The implants are all manufactured by 3i and represent three 'generations' of implant products, i.e. as a function of different geometries and surface treatments. The paper describes that in several instances, the implant types were mixed in the same patient, which suggest an intention to compare performance on a split-mouth basis. In the results section of the paper success rates were reported according to maxilla and mandible, anterior and posterior, implant diameters and implant lengths. The conspicuous detail is that success rates as a function of different implant surface treatment were not presented and not even addressed in the discussion part of the paper. Moreover, the same group of authors had published a previous paper that was referred to in the text, in which the first and second generation implants were compared (92 per cent *vs* 94 per cent survival after three years)[95]. Although it is not clear whether the second paper encompasses the three-year study sample, one may deduce that a significant improvement of treatment success was not achieved with the newest 'generation' of implant design.

Studies where implant geometry, material and surface topography influences on the outcome 'osseointegration' are confounded.

In Finland a national register for dental implants was initiated in 1994 and administrated by the National Agency for Medicines. Systematically collected data on the numbers of placed and removed implants in the period between 1994 and 2000 have been recorded[96]. The agency claims a fairly high reporting compliance verified by comparisons with the sales figures reported by the manufacturers and importers of dental implants in Finland. During the period, 43,533 implant placements and 808 removals has been registered (1.9 per cent failure). Three existing implant brands had a higher proportion of removals than this average (Brånemark system® 324/8,075 = 4.0 per cent, IMZ® 63/1,812 = 3.5 per cent and Frialit® 2 39/1,533 = 2.5 per cent. Implant brands with a lower than the mean removal rate were e.g. ITI® (199/17,270 = 1.2 per cent), Astra Tech (77/7,289 = 1.1 per cent), and 3i (11/1,229 = 0.9 per cent). The validity of employing these data as indicators of estimations of clinical performance of different implants can be debated. If the dentists in Finland underreport implant failures these data may overestimate success. It can also be argued that the data may be underestimates of implant treatment success if primarily retrospective updating of negative events take place, i.e. the dentists do not bother to report treatment success but report only when some failure may occur.

Valentini and Abensur[67] compared IMZ® titanium plasma spray-coated cylindrical (n=133) and Brånemark system® (n=54) implants placed in sinuses grafted with anorganic bovine bone mixed with demineralised freeze-dried bone allograft (DFDBA) or with anorganic bovine bone alone. The survival rates were similar for the two implant types in sinuses grafted with anorganic bovine bone alone after approximately seven years.

Two different surface treatments of ZL-Duraplant implants in 137 patients were evaluated in a trial over 2–6 years[18,61]. Two implant geometries were used, thus creating study groups consisting of surface treated cylinders (n=30), and screws with (n=339) and without (n=58) surface treatments. The surface treatment is electrochemical and recognised by the trademark 'Ticer®'. 'Failure' was defined as explanted implant. Similar performance was first noted to begin with, but the cylinders demonstrated poorer results than the screws after approximately one year. Moreover, the surface-treated screws performed better than the untreated screws according to the survival statistics ($p<0.05$). Lack of detail prevents calculations of exact estimates of initial osseointegration rates as well as more long-term treatment outcome success.

Noack *et al.*[64] reported on the success of osseointegrated implants of the Brånemark system®, Frialit®-1 (Tubinger Implant), Frialit®-2, IMZ® systems and Linkow blade implants. The lowest loss rates were seen with implants in intermediate and distal extension spaces and with single-tooth replacements using IMZ®, Frialit®-2, and Brånemark system® implants. In edentulous arches, implants of the IMZ® and Brånemark system® implants had the lowest failure rates.

Scurria *et al.*[65] presented retrospective data from a multicentre patient pool, consisting of 384 implants in 99 patients. Most of the implants were Brånemark system® (80 per cent), while the remaining were IMZ® implants. Uni- and multivariate log-rank and Wilcoxon's tests of the survival data indicated no difference between the implant types. However, the heterogeneity of the study material and small size of one of the samples suggests that this would be difficult to detect unless large variable effects were present.

Gómez-Roman *et al.*[58] reported results after treating 159 patients with a mandibular overdenture retained by implants placed between the mental foramina. Three implant systems (IMZ® (n=168), ITI® Bonefit (n=150) and ITI® TPS (n=109) had been in use over a 10 year period. The loss of implants was in general very low, (n=8 in 5 patients) with a slightly poorer

outcome of the TPS implants compared to the two other systems observed over 10 years.

Astra Tech Tioblast® screw (n=31) and ITI® hollow screw (n=93) implants placed in 19 and 56 patients respectively were evaluated by Ellegaard *et al.*[59,60]. The aim of the study was to evaluate the implants placed following a sinus membrane lift versus the ones without additional surgery in periodontally compromised patients. Although the authors write that it was not the intention to compare the two systems, most of the results section as well as the statistics in the report actually focus on this aspect. Univariate survival statistics indicate no differences between the systems for most of the evaluated variables, i.e. implant loss, bone loss, pocket depth, bleeding on probing and plaque deposits. This is hardly surprising in view of the small sample sizes. The additional confounding by differences in patient selection, treatment learning curves, differences in implant lengths and intra-oral location etc. invalidates both the use of the statistics as well as any conclusions forwarded by this study regarding comparisons of implant systems.

Titanium plasma sprayed ITI® (n=36) and IMZ® (n=264) implants with three different geometries followed up between six months and 11 years was reported by Spiekerman *et al.*[66]. Due to the retrospective study design, changes of operators and variable learning curves, patient drop-out and selective placements of implants according to the initial treatment situation one may question the reliability of making any comparisons. Moreover, the implant geometries have changed since this study was carried out, and only one of these (IMZ®, 3.3 mm) is still available today.

De Bruyn *et al.*[57] described the performance of implants placed by the main author in a private practice. The author first employed Screw Vent® and Swede Vent® implants (Core Vent Company), of which he placed 85 and 11 implants in 31 patients before changing to Brånemark system® implants (n=107) in 25 patients. This report actually describes two separate case series and although the authors compare the outcomes of the two systems, factors such as patient selection, treatment learning curve, differences in implant lengths and intra-oral location etc. exclude any meaningful conclusions. Moreover, incomplete reporting of patient compliance and drop-outs, different length of the observation periods, small sample sizes and lack of statistical analyses invalidate many of the authors' conclusions about implant comparability. Finally, the Screw Vent® implant that today is manufactured by Centerpulse and has another geometry to the one used in this clinical study.

A paper by d'Hoedt and Schulte[97] presented follow-up results from five implant systems, but the report is of limited value today. Most of the implants evaluated are no longer in production (Frialit Tübingen® and ITI® E, K & H-types) and the other implants are early generations of modern type implants (IMZ®, ITI® TPS and Brånemark system® implants), with relatively short follow-up time. Moreover, the report lacks details about the observed failure patterns and does not present comprehensive documentation of the clinical performance for all five implant systems, but rather focuses on highlighting the performance of one of the implant systems.

3. Aesthetics

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

Category A1 studies: Randomised controlled trials

Studies where implant geometry, material and surface topography influences on the outcome 'aesthetics' are confounded.

Astra abutments were used for the Astra Tech implants (n=46) and standard ITI® solid abutments as well as ITI® Octa abutments were used on ITI® implants (n=56) to retain single crowns in 82 patients[27]. No differences were noted regarding patient satisfaction with the aesthetics after one-year of observation.

Category A2 studies: Split-mouth randomised design

Implant material influence on the outcome 'aesthetics'.

Ceramic (n=44) versus titanium (n=44) abutments placed on single tooth Brånemark system® implants were compared in a trial using a combined parallel and split mouth RCT study design[86]. No differences were observed regarding aesthetics at one and three year follow-up observations.

4. Peri-implant mucositis

Summary: 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 same conclusion applies to influence of implant/abutment surface topography, evaluated in on three split-mouth RCTs. Implants with different geometry, material and surface topographies were evaluated in six RCTs and three 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.

Category A1 studies: Randomised controlled trials

Implant geometry influence on the outcome 'peri-implant mucositis'.

Cylinder IMZ® with TPS coating and ITI® solid screw implants with TPS coating were placed in the mandibles of 40 patients with moderate jaw resorption and overdentures retained by bar and clip attachments were made after

three months[32]. Signs of peri-implant mucositis were similar in the two groups, which was also corroborated by microbiological findings in the three-month report[32], and over one year[33] and two years[31].

Gatti and Chiapasco[85] compared two-piece and one-piece transmucosal Brånemark system® implants that had been immediately loaded with an overdenture. Five patients in each group received four implants each. No differences were noted regarding periodontal indices after one and two years, but the sample size was so small that this study should be regarded as a pilot study only.

Studies where implant geometry, material and surface topography influences on the outcome 'peri-implant mucositis' are confounded.

Brånemark system® MKII (n=187) and Astra Tech Tioblast® (n=184) implants in 66 patients demonstrated no significant differences with regard to peri-implant mucositis after one year and three years[26], and five years[25].

Southern and Sterioss implants demonstrated similar prevalences of peri-implant mucositis around pairs of implants retaining mandibular overdentures after one[16] and two years[30].

Fixed partial dentures were fabricated on Brånemark system® and ITI® hollow screw implants placed in the mandible of 40 completely edentulous patients. The degree of peri-implant mucositis over three years was similar[29].

Meijer *et al.*[28] presented five-year data of edentulous patients fitted with a mandibular overdenture either retained by two IMZ® (29 patients) or two Brånemark system® implants (n=32). No differences were noted with regard to different periodontal indices, i.e. plaque, gingival, bleeding and calculus indices and probing depth. Hollow screw ITI®, Brånemark system® and IMZ® implants in three groups of 30 patients provided with a mandibular overdenture retained by a bar-clip on pairs of implant abutments presented no differences with regard to peri-implant mucositis at one year[24]. Astra Tech (n=46) and ITI® hollow screw and hollow cylinder (n=56) single tooth implants in different intra-oral regions of 82 patients showed same degree of peri-implant mucositis after one-year of observation[27].

Category A2 studies: Split-mouth randomised design

Implant material influence on the outcome 'peri-implant mucositis'.

Ceramic (n=44) versus titanium (n=44) abutments placed on single tooth Brånemark system® implants demonstrated no differences regarding measurements of various indices of peri-implant tissue health after one year and three years[86].

Barclay *et al.*[87] selected 14 patients who had been provided with a mandibular denture retained by a Dolder-bar on two IMZ® implants for at least 12 months. Each pair of abutments was replaced with a ceramic-coated abutment or a new conventional one and soft tissue parameters were recorded over the next 12 weeks. No differences were noted with regard to peri-implant mucositis, although the authors concluded that the soft tissue response 'may vary in features that are not apparent when assessed by conventional clinical parameters'.

A group of investigators in Leuven, Belgium, has carried out extensive studies on abutments with different surface topographies and chemistry and possible influences on soft tissues by applying a range of different outcome criteria. Clinical criteria were reported by Bollen *et al.*[88] who followed six patients provided with a mandibular overdenture retained by pairs of a ceramic and a titanium abutment for one year and noted no clinically significant differences regarding soft-tissue response.

Implant surface topography influence on the outcome 'peri-implant mucositis'.

The soft-tissue response was similar for four different titanium implants with different degrees of surface roughness when observed over three months[89]. The author emphasises that the findings applies only for titanium abutments with a low surface roughness, i.e. less than Ra=0,20. The conclusions were corroborated by other studies where microbiological outcome criteria have been used.

Sandblasted and acid-etched (SLA) (n=68) and titanium plasma sprayed (TPS) (n=68) ITI® implants of the same geometry placed in the posterior edentulous regions in the mandible and provided with fixed bridges showed identical presence of peri-implant mucositis over one year[14].

Turned and TiO_2-blasted Astra Tech implants retaining fixed partial dentures demonstrated no significant difference regarding peri-implant mucositis over five years. At baseline 5 per cent of the TiO_2-blasted implants and none of the turned implants showed signs of peri-implant mucositis. After one year the respective figures were 12 per cent and 9 per cent, after 3 years 12 per cent and 4 per cent and after 5 years 6 per cent in both groups[46].

Studies where implant geometry, material and surface topography influences on the outcome 'peri-implant mucositis' are confounded.

Jeffcoat *et al.*[40] compared 615 implants placed in 120 edentulous patients. Each patient received five or six Brånemark system® or a hydroxyapatite-coated threaded or cylindric implant of an unknown brand. No differences were noted with regard to periodontal indices over one to five years.

Geurs *et al.*[39] followed 120 healthy edentulous patients that each had received five or six implants in the anterior mandible for three years. At least one implant was either a threaded titanium plasma-sprayed (Steri-Oss), or a threaded or cylindric HA-coated implant of unknown brand. After three years, periodontal indices of 470 of the originally 634 placed implants were reported and no differences were noted.

Astra Tech Tioblast® (n=50) and Brånemark system® MKII (n=45) implants were reported to be comparable with regard to probing pocket depth, plaque and bleeding on probing over two years observation[44].

Category C studies: Clinical studies with other study designs

Studies where implant geometry, material and surface topography influences on the outcome 'peri-implant mucositis' are confounded.

Two different surface treatments of 497 ZL-Duraplant screw and cylinder implants placed in 137 patients could not be associated with different criteria used to describe peri-implant mucositis, i.e. papilla bleeding, probing depth and sulcus fluid flow rates over a follow up period of two to six years[61].

Astra Tech and Brånemark system® single tooth implants that had been in function for a minimum of two years in 30 patients were examined by Puchades-Roman *et al.*[62]. Bleeding on probing was similar for both implant brands. A difference in probing depth was observed (Brånemark 3.3mm *vs* Astra Tech 2.7mm, p= 0.03). The authors attributed this to probable disparity in biologic width relative to the implant geometries.

5. Marginal bone loss

Summary: Implant geometry influence on marginal bone loss has been appraised in two RCTs, but with short observation periods and no difference between geometries. Influence of abutment/implant material has only 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. Finally, several studies where implants with different geometry, material and surface topographies have been evaluated using a RCT design (n=6) 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. A few non-randomised controlled clinical trials (n=4), on the other hand, 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 utilising less rigorous study designs should be recognised.

Category A1 studies: Randomised controlled trials

Implant geometry influence on the outcome 'marginal bone loss'.

IMZ® cylinder implants with a TPS coating or ITI® solid screw implants with TPS coating placed in the mandible to retain overdentures by bar and clip attachments demonstrated similar mean bone loss (0.6mm) after one year[32]. The loss after two years was 1.1mm for the IMZ® 1-stage, 0.8mm for IMZ® 2-stage and 1.2mm for ITI® (one stage)[31]. The relatively short observation period restricts any generalisation about the influence of geometry on marginal bone loss.

Gatti and Chiapasco[85] compared, over two years, two-piece and one-piece transmucosal Brånemark system® implants in two groups of five patients each. Four implants were placed in each mandible and immediately loaded with an overdenture. The bone resorption did not differ statistically between the two groups, which is hardly surprising considering the small sample sizes.

Implant surface topography influence on the outcome 'marginal bone loss'.

TiUnite (n=66) and turned Brånemark system® (n=55) implants were placed in the posterior mandibles in 44 patients and immediate loading was applied with partial fixed bridges[37]. The marginal bone resorption after one year of loading was on average 0.9mm with the TiUnite implants and 1.0mm with the turned implants.

Studies where implant geometry, material and surface topography influences on the outcome 'marginal bone loss' are confounded.

Astra Tech and Brånemark system® implants used for maxillary and/or mandibular reconstruction revealed no significant differences in bone loss either in the maxilla or the mandible at one year (Astra Tech 1.6mm, Brånemark 1.9mm)[25], three years (Astra Tech 1.5mm, Brånemark 1.8mm)[25] and five years[26]. The greater bone loss following abutment connection for the Brånemark system® was likely due to more flap reflection.

Southern and Sterioss implants demonstrated similar bone loss after one and two years around pairs of implants retaining mandibular overdentures[16,30]. It is unclear as to whether differences in implant surface topography or implant geometry between the two tested implants or different types of retaining abutments on the implants confound the observed clinical outcome.

Astra Tech (n=46) and ITI® hollow screw and hollow cylinder (n=56) implants were restored with single crowns following a six-month period of healing. The baseline radiographs taken one week after crown placement were compared to radiographs taken at one year[27]. The marginal bone loss was similar for both implant brands (0.1mm).

Brånemark system® implants and ITI® hollow screw implants placed in the mandible were compared in 40 edentulous patients[29]. Reconstructions were full arch prostheses and radiographs were obtained at prosthesis insertion, one, and three years. The results revealed no significant difference between the implant systems at three years. Four implants exhibited progressive bone loss (three ITI® and one Brånemark) and 13 implants had measurable marginal bone loss at three years (three ITI® and eight Brånemark). The

remaining implants either exhibited no marginal bone changes or bone gain.

Meijer *et al.*[28] presented five-year data of edentulous patients fitted with a mandibular overdenture either retained by two IMZ® implants (29 patients) or two Brånemark system® implants (n=32). The bone loss was not presented as mean values in the paper, but the authors reported that it did not differ between the two groups after five years.

ITI®, Brånemark system® and IMZ® screw implants were placed in pairs in 30 patients with an edentulous mandible to support an overdenture. Based on a standardised technique, significantly less bone loss was recorded at 12 months with the ITI® implant (0.2mm) compared with either the Brånemark system® implant (0.3mm) or the IMZ® implant (0.5mm)[24].

Category A2 studies: Split-mouth randomised design

Implant material influence on the outcome 'marginal bone loss'.

Ceramic (n=44) versus titanium (n=44) abutments placed on single tooth Brånemark system® implants were compared in a trial using a combined parallel and split mouth RCT study design[86]. No differences were observed regarding bone loss measurements, which amounted to about 0.1mm on average, but with a wide variance of bone loss among patients (SD up to 0.6mm).

Implant surface topography influence on the outcome 'marginal bone loss'.

Turned and TiO_2-blasted (Tioblast®) Astra Tech implants supporting fixed partial dentures were compared annually for five years[46]. Radiographs were made using a standardised technique. One observer blinded to the implant surface measured the marginal bone loss. The observed bone loss exhibited no significant different between the systems at five years. The turned implant bone loss was 0.2mm both in the maxilla and the mandible, while the comparable loss for the TiO_2-blasted implants was 0.5mm.

Sandblasted and acid-etched (SLA) (n=68) and plasma sprayed (TPS) (n=68) implants of the same geometry (ITI®) were placed in the posterior edentulous regions in the mandible. At the one-year follow-up the accumulated bone height levels showed a mean marginal bone loss of 0.6mm (SLA) and 0.8mm (TPS) implants[14]. The short observation period restrict further generalisation about the influence of surface topography on bone loss.

Studies where implant geometry, material and surface topography influences on the outcome 'marginal bone loss' are confounded.

Jeffcoat *et al.*[40] compared hydroxyapatite-coated threaded and HA-coated cylindric implants of an unknown brand with Brånemark system® implants in 120 edentulous patients. Each patient received five or six implants, of which at least one was of each implant. All three implant types had success rates above 95 per cent after five years, when 'failure' was defined as more than 2mm bone loss.

Twenty-eight patients with fixed partial bridges in the maxilla supported by ITI® and Brånemark system® implants on each sides were observed over one year[38]. There was no significant change of the marginal bone (0.2mm, Brånemark system® and 0.1mm, ITI® implants). The author noted that a crater-form bone loss was observed around some of the ITI® implants (18 per cent).

Astra Tech Tioblast® (n=50) and Brånemark system® MKII (n=45) implants placed in 18 patients demonstrated minor differences in the change of the marginal bone levels over two years (0.2mm for Astra Tech versus 0.0mm for Brånemark system® implants)[44].

Category B studies: Clinically controlled trials

Implant geometry influence on the outcome 'marginal bone loss'.

Self-tapping Brånemark system® MKII implants (n=88) demonstrated similar bone loss compared to the standard Brånemark system® implants (n=91) over 0–3 years (0.6mm)[54,55] and over 0–5 years (0.8mm)[56].

Studies where implant geometry, material and surface topography influences on the outcome 'marginal bone loss' are confounded.

Titanium-plasma spray (TPS) ITI® implants and Brånemark system® implants were compared in 3 x 29 patients in a multicentre trial by Becker *et al.*[49]. The patients were treated at three different surgeries that each used their specific surgical technique, i.e. one stage protocol for ITI® implants (n=78), and a one stage (n=80) and a two-stage (n=78) protocol for the Brånemark system® implants. The respective changes in bone crest measurements after approximately 15 months observation were 1.3mm (maxilla) and 1.0mm (mandible) for the ITI® implants. The corresponding figures for the Brånemark system® implants were for the one stage and two stage placement respectively 0.1mm and 0.1mm, and 0.2mm and 0.4mm for the maxilla and the mandible. The authors did not carry out any statistical comparisons between the two implant brands at any stages.

A threaded titanium, a cylinder-shaped titanium with hydroxyapatite plasma-sprayed coating (HA), and a cylinder-shaped titanium plasma-sprayed coating (TPS) implant, all manufactured by 3i, were placed in the anterior mandible of 15 edentulous patients[52]. The TPS implants demonstrated significantly more marginal bone loss at three years than the other implants. Mean marginal bone loss was 0.7mm (range 1-4mm) for the titanium implants, 1.2mm (range 1-4mm) for the HA implants, and 2.5mm (range 1-6mm) for the TPS implants. Images were used, which do not allow precise assessments (especially less than 0.5mm). Thus, the rank order of bone loss is likely to be the more appropriate finding than the actual amount of marginal

bone loss. The three different implants were also applied in a non-submerged application in the edentulous mandible. The baseline time for determination of marginal bone loss was at prosthesis connection. In this study five implants were lost and did not provide data for bone loss. The remaining implants revealed marginal bone loss ranging from 0-3mm after three years. The mean marginal bone loss was 0.3mm (range 0-2mm) for the titanium implants, 0.5mm (range 0–1mm) for the HA implants and 1.5mm (range 0-3mm) for the TPS implants[53]. The findings of this study reinforce the rank order of marginal bone loss seen in the previous study, however direct comparisons of data are complicated by the fact that different baseline times were used.

Category C studies: Clinical studies with other study designs

Implant geometry influence on the outcome 'marginal bone loss'.

Four different geometries of Brånemark system® implants and four different abutments were used to retain 82 single crowns in 58 patients in a retrospective study[70]. Greater bone loss was seen around a conical type implant compared to the implants with other geometries over two years, i.e. 1.2mm versus 0.6mm the first year and +0.2mm and +0.1mm the second years.

A similar study design was carried out in Belgium[73] reporting the results of 84 single crowns on Brånemark system® implants with four different geometries placed in 75 patients and followed over three years. More bone loss was recorded around the conical implants (1.9mm) versus the other self-tapping designed implants (0.6mm).

6. Mechanical problems of the implant - abutment - superstructure connections

Summary: The low incidence of mechanical problems reported in four RCTs precludes any general conclusions. The single split-mouth RCT suggest that ceramic abutments may be more prone to mechanical problems than metallic ones during placement, but once this is overcome, the clinical performance is comparable. A 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 recognised.

Category A1 studies: Randomised controlled trials

Implant geometry influence on the outcome 'mechanical problems'.

Cylinder IMZ® with TPS coating and ITI® solid screw implants with TPS coating were placed in the mandibles of 40 patients with moderate jaw resorption and overdentures retained by bar and clip attachments were made after three months[31]. During the one year observation period, significantly more mechanical problems were encountered with the IMZ® system, mainly related to the healing caps.

Studies where implant geometry, material and surface topography influences on the outcome 'mechanical problems' are confounded.

Brånemark system® MKII and Astra Tech implants (n=184+187) placed in 66 edentulous patients to receive fixed prostheses demonstrated comparable and low levels of mechanical complications over five years[25,26].

Brånemark system® and ITI® hollow screw (n=102+106) implants placed in the mandible of 40 edentulous patients to receive fixed prostheses showed similar very low incidence of mechanical complications over three years[29].

Meijer *et al.*[28] reported that multiple prosthetic revisions were necessary over five years in a group of edentulous patients fitted with a mandibular overdenture either retained by two IMZ® implants (29 patients) or two Brånemark system® implants (n=32). Broken abutments were more frequent for the IMZ® implants.

Category A2 studies: Split-mouth randomised design

Implant material influence on the outcome 'mechanical problems'.

Andersson *et al.*[86] compared in a trial using a combined parallel and a split mouth RCT study design 44 ceramic versus 44 titanium abutments placed on Brånemark system® implants. Several fractures of the ceramic abutments were experienced during the abutment placement (5/34), but comparable performance was noted over the next three years.

Category B studies: Clinically controlled trials

Implant geometry influence on the outcome 'ease of placement'.

In a 5–7 year follow-up of 429 HA-coated cylindric implants (Omniloc) placed into 121 patients the mechanical failure rate was significantly higher for implants with angled abutments (21 per cent) versus straight abutments (3 per cent)[90].

Category C studies: Clinical studies with other study designs

Implant geometry influence on the outcome 'mechanical problems'.

Bambini *et al.*[92] compared two systems for interfacing the abutment described as being 'antirotational', i.e. 'Spline®' and 'Threadloc®' systems. Implants were placed only in mandibular sites in edentulous areas originally occupied by first bicuspid to second molar teeth. Twenty-seven patients had 44 Threadloc® implants and 32 patients had 52 Spline® implants. After three years, three single Threadloc® implants (20 per cent) and five pairs of joint Threadloc® implants (6 per cent) showed problems and a possible prosthetic screw loosening. With the Spline® series, no screw loosening was encountered. The study concluded that the Spline® system was more 'stable' than the

Threadloc® system. However, the study made the interesting remark that: "problem cases were solved by increasing the torque from 30 to 35ncm, and in accordance with other studies, clinical screw joint stability was improved without changing the geometry of the implant/abutment interface." Thus, the relevance of the initial findings can be debated.

Retrospective case series evaluations of single tooth and partially edentulous jaws report that older types of abutments demonstrated more loose screws than the newer abutments with other geometries[68,93,94]. Although studies with a retrospective design introduce the risk of several varieties of study bias, it is a fact that manufacturers have continuously modified the geometric designs of the abutments and screws, one may presume as a response to feedback from clinicians experiencing specific mechanical problems with implant systems.

Studies where implant geometry, material and surface topography influences on the outcome 'mechanical problems' are confounded.

Krausse *et al.*[63] compared the requirement for maintenance, modification, repair or remake of the implant-supported overdentures made for 46 edentulous patients over eight years. Implants were either Brånemark system® (n=90) or ITI® (n=32). Less maintenance was required for the Brånemark system® implants (67 per cent remained unrepaired) compared to the ITI® implants (55 per cent).

Behr *et al.*[91] demonstrated the importance of having precise fitting, non-resilient abutment components leading to rigid connections of suprastructures instead of a resilient design. In a retrospective study with up to eight years follow-up the rate of mechanical complications of 138 ITI® implants was significantly lower (13 per cent) than for 50 IMZ® implants with resilient anchoring components (71 per cent).

7. Mechanical failing of dental implants

Summary: One RCT and one split-mouth RCT and a few trials based on other study designs provide information on fracture incidence. The findings provide little information on the possible relationship between implant characteristics and mechanical failing of the implant.

Category A1 studies: Randomised controlled trials

Implant material influence on the outcome 'mechanical failing of implant'.

IMZ® implants with hydroxyapatite (n=89) or titanium plasma-flame coating (n=100) supporting three-unit premolar-implant bridges in partially edentulous mandibles were compared over more than three years by Mau *et al.*[36]. The fracture rates were reported to be comparable, i.e. 0.3 per cent and 0.1 per cent respectively. (Percentages calculated from the total number of implant inspections over 3–7 years). It is slightly unclear from the text whether the rates represent only bulk, i.e. horizontal, or also partial fractures.

Category A2 studies: Split-mouth randomised design

Implant surface topography influence on the outcome 'mechanical failing of implant'.

Gotfredsen and Karlsson[46] reported in their study on fixed partial dentures retained by 133 turned and TiO_2 -blasted Astra Tech implants that two of the turned implants fractured within the first two years of function. No further fractures occurred during the five year observation period.

Category C studies: Clinical studies with other study designs

Studies where implant geometry, material and surface topography influences on the outcome 'mechanical failing of implant' are confounded.

The Finnish implant register indicates that approximately 35 implants has been removed due to fracture between 1996 and 2000. This constitutes 0.4 per cent of the removed implants during the period (n=808). This is a remarkably low number in view of the fact that 43,553 implants has been placed during the same period. The register does not report whether a specific implant brand is over-represented in this figure[96].

Other long-term clinical retrospective studies corroborate that implant fracture is a rare incidence. Naert *et al.*[76,77] report 0.9 per cent over 16 years (mean 5.5 years) for Brånemark system® implants in partial edentulous situations. Eckert *et al.*[98] reported a 0.6 per cent fracture rate of 4,937 Brånemark system® implants in the maxilla and the mandible and with the highest fracture rate in partially edentulous patients (1.5 per cent) versus 0.2 per cent in full edentulous jaws. Bahat[99] reported 0.2 per cent fractures over 5-12 years of Brånemark system® implants in the posterior jaw. Balshi[100] reported a similar incidence, also for Brånemark system® implants. A higher incidence of fractures is associated with location in the posterior region, fixed partial dentures supported by one or two implants with cantilever load magnification and bruxism or heavy occlusal forces[5].

Discussion

Promotional material

Only a few manufacturers produce brochures that contain references to scientific studies documenting the performance of their products and/or present objective information supported by research reports, or present this on their website. Moreover, rather surprisingly, relatively few websites inform to what extent the manufacturers and/or products comply with international standards (*Table 5*). Many countries require proof of product or producer adherence to a standard in order to be marketed. One reason is perhaps that most well established manufacturers may consider such information in their

promotional material as redundant because the CE mark is mandatory for marketing a product in Europe and a FDA approval for USA respectively.

Standardisation

Standards relevant to the manufacturing of dental implants fall into two categories, either quality assurance of the manufacturing process or directly applicable to the actual implant or components of the implant system. The first category of standards centres on the manufacturing process with focus on for example, development, production, installation, servicing and documentation (e.g. ISO9001, ISO9002, EN46001, EN46002, ISO13485). The majority of manufacturers comply with these standards (*Table 5*). Accredited certification bodies (synonymous to 'notified bodies') verify and control that the manufacturers adhere to such standards. The equivalent concept in the USA is an adherence to the Good Manufacturing Practice (GMP), which is regulated by the Food and Drug Administration (FDA). Both standards involve possible on-the-spot inspections of the product facilities. It is important to note that these standards contain no requirements to the end product i.e. the actual dental implant.

Marketing a product in the USA requires the submission of a pre-market notification (510(K) statement) to FDA. This consists in essence of documentation 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 submissions of endosseous implants are indications for use, device description and sterilisation information. Upon request the manufacturer must also provide data on mechanical, corrosion and biocompatibility testing, as well as characterisation of any coatings used. Further requests may also include documentation of test reports as well as data from animal and five-year clinical studies. Additional requirements need to be fulfilled if the implant coating includes calcium phosphate. The FDA are currently revising the requirements and one proposal is that the current prerequisite for five-year clinical data can be reduced to three years with the implant under loaded conditions (www.fda.gov/cdrh/ode/guidance/1389.html).

In Europe, a common system for all member countries of the European Union (EU) replaced in 1998 all national certification programmes for dental products that were in existence. This system is based on an EC council directive (ED93/42/EEC) pertaining to medical devices. The directive includes dental products and is in essence a demand that all medical devices need to be accredited by a certified body before marketing and sale within the EU. All medical devices are categorised into class 1, 2a, 2b and 3 depending on the risk of potential adverse biological effects, and the required documentation of safety and effectiveness is lowest for class 1 products and increases with higher classification. Dental implants are placed in category 2b. The proof of an accreditation is the CE label, and once obtained, the product can be sold without any trade barriers within EU. The producer can chose one of two alternatives to obtain the CE-label. Alternative one is to have their quality assurance system for the production inspected and appraised by a controlling body. In practice, the assessment is done relative to the quality system standards ISO 9001 or the European equivalent EN46001. Alternative two is to have the actual product certified. The problem with this approach is that there are few requirements and the implants are only tested to see whether they reflect the product descriptions supplied by the manufacturer.

The European standard EN1642 – Dental implants includes requirements for (1) intended performance, (2) design and properties, including add-on components, (3) sterilisation and packaging, (4) marking, labelling and information supplied by the manufacturer that include: 1. Documentation that a risk assessment has been carried out e.g. according to a specific ISO procedure (EN-ISO14971), 2. Materials need to comply with property requirements needed for implants, described in two ISO technical files (EN-ISO10451 and EN-ISO14727) and must be assessed for biocompatibility according to specific usage tests described in other ISO documents (EN-ISO7405 and EN-ISO10993). The prefabricated parts intended to connect a suprastructure to dental implants need to comply with property requirements described in more detail in an ISO technical file (EN-ISO14727), 3. Dental implants need not be manufactured under sterile conditions or supplied sterile, but the condition in which they are supplied requires clear description on the package. Guidance for sterilisation methods is described in ISO documents (EN550, EN552, EN556) and 4. The information required needs to comply with details regarding use of symbols and minimum information on labelling and instructions for use.

In practice, an overwhelming majority of all certification processes are focused on the production process and not on the end products. None of the manufacturers advertised on their websites or in their promotional printed materials that their products complied with EN1642. This signifies that the traditional independent testing of products according to various standards often are not carried out since the EU directive does not explicitly instruct that this needs to be done. European authorities do not implement additional requirements beyond the CE-label. It can be speculated whether the present regulatory systems in USA and

Europe can account for the fact that the large majority of the dental implant brands lack solid clinical documentation of beneficial effects for the patient (Code A in *Table 5*). It is even apparent that implant systems can be marketed in EU with the current legislation system without any documentation of clinical performance at all in well-known peer-reviewed scientific journals (Code D in *Table 5*).

Clinical documentation

Only approximately ten implant systems were clinically documented in accordance with that which we described as extensive. Moreover, it can even be argued that the criteria applied in this paper to define 'extensive clinical documentation' is not rigorous enough, i.e. more than four prospective and/or retrospective clinical trials (Code A in *Table 5*).

Some venture that more than four studies are needed to verify the results of implant systems used in a variety of indications combined with surgical techniques appropriate today[101]. Moreover, although the identified systems received this classification code, it does not mean that they are equivalent in clinical performance. It just signifies that the clinical performance of the system has been documented in peer-reviewed journals, not necessarily shown to exhibit high clinical performance. The reliability of applying the coding of A to D in *Table 5* to different implant systems can also be debated. We acknowledge that it is impossible to draw strict criteria between when an implant brand can be considered extensively documented versus the next level of evidence of documentation etc, so the subjective nature of this categorisation is recognised.

One needs also to take into consideration that the output of new research findings is not static, so *Table 5* needs to be interpreted with some caution. What remains, however, is that among the many implant systems marketed today, only a minority is adequately documented scientifically, and worse, many implant systems are marketed without any clinical documentation at all of the alleged clinical benefit for patients.

In general, a substantial number of claims made by different manufacturers on claimed superiority due to implant geometry, material and surface treatment are not based on sound clinical scientific research. We have deliberately not included specific examples of claims made by named manufacturers of clinical superiority related to particular implant features for two reasons. Firstly, because we regard to label specific manufacturers selectively is contra-productive, and secondly because the contents of advertisement and on websites change continuously.

Implant characterisation

Categorising implants according to their geometry is a complex task, especially when also taking into account that many implants display variations along the vertical axis due to selective different surface treatments. Systems for classification of implants can be constructed according to morphological differences. However, 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 categorisation system for dental implants. This calls for a very critical appraisal of the relevance of different implant characteristics for the clinical performance. Ideally, the manufacturer should provide this information, but regrettably this is not usually the case. The rationale for the continuous redesigning of new geometric shapes is often based on finite element studies and also, for particular implants, histological evaluations in animal studies. The validity of these studies to predict clinically significant improvements remains uncertain. On the other hand, the few clinical studies that do exist do not clearly identify implant geometry as an important factor when it comes to treatment success.

Implant material

The majority of manufacturers today limit the production to c.p. titanium implants and many manufacturers who previously sold an array of titanium, titanium-alloy, and calcium-phosphate implants have discontinued manufacturing the last category. One may infer that c.p. titanium and titanium-alloy with or without a hydroxyapatite coating are the materials of choice for dental implants. Dental implants made from any other material should not be used if the manufacturer cannot demonstrate scientifically sound evidence of an at-least equivalent clinical record compared to titanium-based implants.

Implant surface treatment

Although one may suspect that marketing distinction can be a driving force for promoting new and alternative surface-treated dental implants this issue is complex. One must bear in mind that the science on integration between bone tissues and alloplasts is relatively young. New knowledge and alternative hypotheses have been generated continuously during the last decades, but the research community still does not understand the exact biological mechanisms that regulate and control optimal bone integration.

The first implants made in the mid-1970s were machined with a turning process, and several manufacturers attempted to replicate this manufacturing practice. Today, several manufacturers have abandoned this method in preference for different surface treatments. This decision is mainly based on results

from various experimental studies showing faster and firmer bone fixation for surface enlarged implants. The clinical reason for using the new surface modifications is the possibility of speeding up the healing process and loading the surface modified implants at an earlier time than generally recommended for turned implants.

Influence of implant characteristics on clinical performance

Differences in quality of dental implants may or may not have an influence on clinical success, and these differences will be reflected by different problems encountered at the different phases of the treatment. A few implant manufacturers carry out elaborate animal and/or laboratory studies to minimise the risk of a non-predictive clinical outcome. Such experimental data must be confirmed by clinical observations reported in peer-reviewed scientific journals. The reporting of results in company-sponsored literature alone is not sufficient and should be appraised very critically.

'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 non-self-tapping implants, and claims of benefit of specific implant apex morphologies related to primary implant stability. The clinical sign of a 'difficult placement' is conceivably a lack of primary implant stability. Regarding the first issue, the choice of a tapered versus a straight implant is more a question of correct diagnosis and proper treatment planning rather than an indication of implant quality *per se*. Thus this feature cannot be regarded as an indication of 'good' and 'less good' implant quality. Primary implant stability can reflect how well the site was prepared to receive the actual implant rather than quality marks of the implant *per se*. It is critical that the exact set of burs relevant to the implant product is employed and that they are not worn. Moreover, any deviations from the standard site preparation procedure as advocated by the manufacturer for the specific implant system, either accidentally or intentionally, will jeopardise the primary stability of the inserted implant.

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. Moreover, 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'. Finally, it should be noted that 'ease of placement' is not necessarily related to 'time'. Any surgical procedure that increases the risk for overheating of bone is definitely not recommended.

The most important outcome following an implant installation is of course that the implant osseointegrates with a high degree of predictability. An additional focus today, however, is how fast this osseointegration can be achieved. 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. Rather few studies present data from long time follow-up, i.e. more than five years, and the few that are available can at best be characterised as prospective case series of single implants, and 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 that have been followed for five years, and to date none beyond five year's observation. That the short Brånemark system® implants failed more frequently than longer implants was reported in most clinical reports in the 1980s and early1990s, both in controlled clinical trials as well as in case series descriptions[54,65,78,103]. Other studies evaluating other implants associate also more failures to 'short' implants, e.g. Omniloc implants[90], ITI® implants[71], Bicon implants[82] and 3i turned implants[104]. One must pay attention to the term 'short', which in some papers means implants 6–7mm in length, while in others the term 'shorter' can be defined as anything less than, for example, 14mm[72].

Some manufacturers highlight that this is not the case with their products. Such claims needs careful evaluation since reports often cited to support such claims have either severe statistical flaws or are methodologically weak. For example, ITI® advertisements cite one large study with extensive follow-up time[19], but the paper lacks proper multivariate survival statistics such as Cox regression or proportional hazards modelling. Another example is a study evaluating Osseotite® implants where the authors emphasised that 'the shorter implants performed similarly to longer implants', although the study was not designed to address that issue[13].

An intriguing finding is that an investigator group in Leuven, Belgium, who earlier reported an association between implant length and failure risk, do not demonstrate such a clear relationship following a reanalysis of the study material using more complex multivariate statistics[74,75]. It has even been reported in a recent clinical study that the failure of Brånemark system® implants in this study was more frequent among the *longer* (15–18mm) compared to the shorter implants[79].

What must be remembered is that any study with a retrospective design is at risk from potential

recall and examiner bias. Moreover, any demonstrable numerical relationship between two clinical variables in an often extensive and heterogeneous data set may in theory also be due to confounding clinical or patient factors, or it can be just a spurious statistical phenomenon. A prospective study that addresses the influence of implant length on treatment success, preferably randomised and/or blinded, can provide indications as to the extent to which this may be an aetiological factor for implant failure. As no such studies have been carried out, 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. In other words, implant length is a surrogate variable for what actually represents differences in case and site selections in clinical trials. In the same line of discussion is the controversy of alleged benefit of wide diameter implants. Chuang *et al.*[82] applied multivariate regression on data of 2,349 Bicon implants and associated failures with short implant length, but not with implant diameter. Also Davarpanah *et al.*[105] and Friberg *et al.*[106] reported positive experiences with placing wide implants, while findings from other investigators should caution against their indiscriminate use[107–110]. It has been proposed that different alloy compositions used for different components of the reconstruction can create galvanic effects and thereby cause adverse soft-tissue reactions and perhaps even implant failure[111]. This would theoretically signify that implant systems where this is the case should be avoided. However, the hypothesis remains unconfirmed and is not based on solid clinical evidence.

The clinical significance of the reported differences in bone loss among the implant systems must be considered in relation the fact that reliable bone loss measurements of less than 0.2mm is difficult to achieve, even in *in vitro* situations[112]. Moreover, in many reports the variations in bone loss among the individuals in the study sample varies considerably, as indicated by very large standard deviations (SD). 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. Moreover, short-term results on bone loss require cautious interpretation, especially in studies where one- and two-surgical stages implant systems are being compared[24,27,29,32,33,38]. Short-term studies help to elucidate the physiological remodelling that occurs around implants of different designs, but it is information about the long-term prognosis of an implant that allows the patient to decide whether implant-based prosthetics is a therapy option for them or not. Although it is known that the largest bone loss around implants occurs during the first twelve months following the surgical insertion[113], there is currently no consensus as to what extent results from short-term clinical studies can predict long-term performance of dental implants.

Mechanical problems of the implant/ abutment/ superstructure connections arising as a function of connection morphology are a very complex and much debated topic in the dental literature. The reason is partly due to the lack of systematic collection of prospective clinical data, and the heterogeneity of results presented in the many published case series of single implant or implant system. 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, but the only country to have implemented this so far is Finland[96]. One may question why other countries have not done the same, especially those that have set up national registers for breast and/or hip implants.

The main engineering goal of abutment designing is to provide what, in the language of basic mechanics, would be termed a 'fixed joint' between implant and abutment. That is, one that can resist all six components of force and moment applied to the joint during service conditions. In assessing the success or failure of a fixed joint, two questions arise: 'What are the three force and three moment components that are typically applied during service conditions of the joint? and, how well do the various implant-abutment geometries stand up to these service conditions?' The fundamental problem is that full data are lacking on exactly what these loading components really are *in vivo*. Limited data exist, but are insufficient to permit conclusions about *in vivo* loading conditions on implants in every location in the mouth, under all conceivable prosthetic conditions in any given patient[114]. Consequently, it remains difficult to assess laboratory testing of abutment systems without knowing the relationship to loads intraorally. Overall, with laboratory testing of abutment-implant systems of various types, the challenge remains to 'close the loop' in relating laboratory test data to actual clinical conditions. Currently it is premature to make sweeping conclusions about which systems are clinically best without test data linked directly to *in vivo* conditions.

All implants may be subject to mechanical fractures. However, technical failures of implants are relatively sparsely described in the literature[115]. Although there have been a few clinical reports of fracture of the implants, in contrast to the more common fractures of abutment screws and prosthetic screws, fractures are important

because of the significant consequences to the patient. Overload seems not to be an aetiological factor as a cause for implant fracture clinically[116,117].

General aspects of the clinical performance of implants

It must be emphasised that there is an 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[118]. An absolute requirement for the clinician before providing implant therapy is that adequate training has been obtained. Of importance is an awareness of possible risk factors involved, and the knowledge of which patient to refer to more specialised centres and which patient one may cope with based on one's own clinical proficiency. Careful preparation of the implant site with adequate cooling and under adequate asepsis is a precondition for implanting foreign materials into bone. A number of clinical studies have reported a significant influence on the treatment result depending on the skills of the surgeon, which may be separated into erroneous treatment planning or the operator's actual handling skills[103,119,120].

Particular products seem to perform well in the hands of specific clinicians, but fail when used by other operators. This leads to the question whether some implant brands contain 'technique sensitive characteristics', confounding the issue of whether it is inadequate training or technique sensitivity characteristics that explain the lack of success in the hands of other operators. Both lecturers and salespersons promoting specific implants occasionally insinuate that particular implants are 'more forgiving' than others in the sense that the implants perform satisfactorily in spite of highly developed surgical proficiency. It is clearly impossible to conduct clinical studies to clarify such an issue for logistical and ethical reasons. Thus, any claims of superior technique sensitivity cannot be entirely disregarded, but should perhaps be regarded with a certain level of scepticism. Moreover, it has also been suggested that from a clinical or microbiological perspective implant failures seem primarily to be at a patient level rather than at an implant level[121,122,183]. Thus, besides the operator, even tangible and intangible patient aspects may be more relevant aetiological factors in implant failure than the actual implant hardware.

The report of the Finnish national implant register states that the most common reason for implant failure is a lack of osseointegration within the first year after the surgical operation. Latter sudden loss of osseointegration is usually unexpected, and is often not preceded by any clinical observable special event[96]. It is unknown whether the underlying reason may be due to the patient, the operation team, the superconstruction 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. Reasons related to the 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). Finally, 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[96].

Factors besides the implant hardware

Also, other hardware components besides the actual implant body and abutment may influence the clinical result. Several clinical studies have focused on comparing fixed versus removable prostheses on implants or on two versus another number of implants, e.g. four implants. Other studies have appraised cemented versus screw-retained fixed prostheses as well as between different types of attachment systems for removable prostheses. Additional potentially confounding factors identified in laboratory experiments are the effects of the material used for the prosthetic superstructures and/or unpredictable loading due to superstructure misfit. The significance of the presence of, and on the location of, an interface or 'microgap' between the implant and abutment/restoration in 2-piece configurations remains debatable. Several factors may influence the resultant level of the crestal bone under conditions where a gap exists, including possible movements between implant components and the size of the microgap (interface) between the implant and abutment[123]. At present, possible microgaps are not regarded as an aetiological factor in causes of early implant bone loss[113]. Possible other negative elements for a successful clinical result that have been identified in laboratory experiments are the effects of the occlusal anatomy and cantilever situations due to the implants' locations and/or the prosthesis extension, inadequate torque used to tighten screws, etc. These study data are not included in the present paper. It should be acknowledged that at least some of these issues are indirectly associated with design characteristics and differences in component tolerance limits of dental implant systems.

Considerations for future research

The extensive diversity of implant characteristics is not necessarily only a result of manufacturers trying to obtain a brand distinction in fierce commercial competition. Patent

infringement lawsuits have also played an important role during the last decades, especially in the USA. However, the diversity is also a sign of the confusion regarding which implant characteristic should be considered to be clinically important. It is probable that this dilemma will continue until there is consensus on the most appropriate requirements – patient based or clinician based – for minimum clinical performance of this treatment modality[102]. Moreover, until fairly recently, implant manufacturers have been reluctant to support clinical trials where different implant characteristics have been compared and especially if these have included an element of comparison between different manufacturers. The relatively few clinical studies that have been conducted (*Table 3*) have mostly compared different implant brands, whereby the influence on outcome due to implant geometry, material and surface topography is confounded. Few clear conclusions regarding the relative importance of these elements individually can therefore be determined. We will remain ignorant as long as there is lack of clinical trials properly designed to study such basic factors. Added to this complexity is the increasingly common study aim of comparing immediate, early and conventional loading done in one-stage surgery. Apart from the terminology dispute about what should be considered 'early', we may perhaps discover that some combinations of material/geometry/surface-treatment are required for some special treatment situations, while some other combinations may be optimal for others. There is also an ethical dilemma in comparing different implants. One needs a hypothesis that it is possible to offer the patient a better treatment 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 implant from the other. The problem is that historically, a systematic approach to elucidate these mechanisms has not been published in the literature and does not seem to be part of the international research agenda. Finally, 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

The existing scientific clinical documentation should be the major consideration factor for selecting dental implants. However, given that several implant systems seems comparable, it would seem legitimate that dentists should also consider other factors that may be regarded as implant system 'quality' in a broad context. Other factors that may be taken into consideration beyond the scientific data can be:

- Is the manufacturer represented locally and can be consulted easily?
- Can they deliver required products timely and reliably in extraordinary situations?
- The manufacturer's ethical and al reputation. Is the manufacturer's promotion exact, fair and comprehensive?
- Does the manufacturer provide service and training possibilities?
- Ease of use. Are the training requirements for using the implant system intricate?
- Flexibility of applications. Some dentists may prefer a wide selection of alternative prosthodontic options such as o-rings, attachments and choice of screw retained or cemented superconstructions, possibility for cast and cemented abutments, angled abutments and anti-rotational abutments.
- 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?
- 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?
- Costs. The cost of the surgical and prosthetic start-up kit, the cost per implant and per component, and the course/training costs needs to be taken into account. Also the accumulated time required for adjustments and mechanical failures needs to be taken into account as this involves other issues such as patient trust and opportunity cost.

Conclusions

The scientific evidence of the influence of dental implant materials, geometry and surface topography on clinical performance is limited and not particularly methodologically sound. There is therefore little basis for promoting specific implants or implant systems as more or less high quality. However, it would seem prudent to avoid using dental implants with no records of clinical documentation, especially if the manufacturer has not disclosed whether the manufacturing process is carried out according to general principles of good manufacturing practice, e.g. according to the quality assurance systems developed by ISO or FDA.

A general characteristic of the trials identified in this paper is the almost unanimous focus on clinical criteria that address implant level treatment outcomes, rather than prosthesis, patient and societal perspectives. It can be questioned whether many of the outcome criteria described in this paper are in fact only surrogate criteria for treatment success, which in the last

instance is the patient's experience relative to the patient's expectations. Cost-benefit and cost-utility analyses to differentiate between dental implant systems need therefore to be addressed in future research.

References

1. Brånemark PI, Hansson BO, Adell R, *et al.* Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. Stockholm: Almqvist & Wiksell International, 1977.
2. Albrektsson T, Brånemark PI, Hansson HA, *et al.* Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. *Acta Orthop Scand* 1981 **52:** 155–170.
3. Binon PP. Implants and components: entering the new millennium. *Int J Oral Maxillofac Implants* 2000 **15:** 76–94.
4. Sahiwal IG, Woody RD, Benson BW, *et al.* Macro design morphology of endoseous dental implants. *J Prosthet Dent* 2002 **87:** 543–551.
5. Rangert B, Krogh PHJ, Langer B, *et al.* Bending overload and implant fractures: a retrospective clinical analysis. *Int J Oral Maxillofac Implants* 1995 **10:** 326–334.
6. Hallgren C, Sawase T, Ortengren U, *et al.* Histomorphometric and mechanical evaluation of the bone-tissue response to implants prepared with different orientation of surface topography. *Clin Implant Dent Relat Res* 2001 **3:** 194–203.
7. Wennerberg A, Hallgren C, Johansson C, *et al.* A histomorphometric evaluation of screw-shaped implants each prepared with two surface roughness. *Clin Oral Implants Res* 2001 **12:** 128–134.
8. Roos J, Sennerby L, Albrektsson T. An update on the clinical documentation on currently used bone-anchored endosseous implants. *Clinical Update* 1997 **24:** 194–200.
9. Eckert SE, Parein A, Myshin HL, *et al.* Validation of dental implant systems through a review of the literature supplied by system manufacturers. *J Prosthet Dent* 1997 **77:** 271–279.
10. Palmer RM, Palmer PJ, Smith BJ. A 5-year prospective study of Astra single tooth implants. *Clin Oral Implant Res* 2000 **11:** 179–182.
11. Norton MR. A 4–7 year follow-up on the biological and mechanical stability of single tooth implants. *Clin Implant Dent Relat Res* 2001 **3:** 214–220.
12. Sullivan DY, Sherwood RL, Porter SS. Long-term performance of Osseotite implants: A 6-year clinical follow-up. *Compendium* 2001 **22:** 326–333.
13. Testori T, Wiseman L, Woolfe S, *et al.* A prospective multicenter clinical study of the Osseotite implant: four-year interim report. *Int J Oral Maxillofac Implants* 2001 **16:** 193–200.
14. Roccuzzo M, Bunino M, Prioglio F, *et al.* Early loading of sandblasted and acid-etched (SLA) implants: a prospective split-mouth comparative study. *Clin Oral Implants Res* 2001 **12:** 572–578.
15. Cochran DL, Buser D, ten Bruggenkate CM, *et al.* The use of reduced healing times on ITI implants with a sandblasted and acid-etched (SLA) surface: Early results from clinical trials on ITI SLA implants. *Clin Oral Implants Res* 2002 **13:** 144–153.
16. Tawse-Smith A, Payne AG, Kumara R, *et al.* One-stage operative procedure using two different implant systems: a prospective study on implant overdentures in the edentulous mandible. *Clin Implant Dent Relat Res* 2001 **3:** 185–193.
17. Deporter D, Watson P, Pharoah M, *et al.* Ten-year results of a prospective study using porous-surfaced dental implants and a mandibular overdenture. *Clin Implant Dent Relat Res* 2002 **4:** 183–189.
18. Graf HL, Geu B, Knöfler W, *et al.* Klinisches Verhalten des ZL-dura-plant-Implantatsystems mit Ticer Oberfläche. Prospektive Studie Mitteilung 1: Überlebensraten. *Z Zahnärtzl Implant* 2001 **17:** 124–131.
19. Buser D, Mericske-Stern R, Bernard JP, *et al.* Long-term evaluation of non-submerged ITI implants. Part 1: 8-year life table analysis of a prospective multi-center study with 2359 implants. *Clin Oral Implants Res* 1997 **8:** 161–172.
20. Merickse-Stern R, Aerni D, Geering AH, *et al.* Long-term evaluation of sub-merged hollow cylinder implants. Clinical and radiographic results. *Clin Oral Implant Res* 2001 **12:** 252–259.
21. Morra M, Cassinelli C, Bruzzone G, *et al.* Surface chemistry effects of topographic modification of titanium dental implant surfaces: 1. Surface analysis. *Int J Oral Maxillofac Implants* 2003 **18:** 40–45.
22. Esposito M, Coulthard P, Worthington HV, *et al.* Quality Assessment of Randomized Controlled Trials of Oral Implants. *Int J Oral Maxillofacial Implants* 2001 **16:** 783–792.
23. Jokstad A, Esposito M, Coulthard P, *et al.* The Reporting of Randomized Controlled Trials in Prosthodontics. *Int J Prosthodont* 2002 **15:** 230–242.
24. Batenburg RHK, Meijer HJA, Raghoebar GM, *et al.* Mandibular overdentures supported by two Brånemark, IMZ or ITI implants. A prospective comparative preliminary study: one-year results. *Clin Oral Implants Res* 1998 **9:** 374–383.
25. Engquist B, Åstrand P, Dahlgren S, *et al.* Marginal bone reaction to oral implants: a prospective comparative study of Astra Tech and Brånemark system implants. *Clin Oral Implants Res* 2002 **13:** 30–37.
26. Åstrand P, Engquist B, Dahlgren S, *et al.* Astra Tech and Brånemark system implants: a prospective 5-year comparative study. Results after one year. *Clin Implant Dent Relat Res* 1999 **1:** 17–26.
27. Kemppainen P, Eskola S, Ylipaavalniemi P. A comparative prospective clinical study of two single-tooth implants: a preliminary report of 102 implants. *J Prosthet Dent* 1997 **77:** 382–387.
28. Meijer HJ, Raghoebar GM, Van 't Hof MA, *et al.* A controlled clinical trial of implant-retained mandibular overdentures five-years' results of clinical aspects and aftercare of IMZ implants and Branemark implants. *Clin Oral Implants Res* 2000 **11:** 441–447.
29. Moberg LE, Kondell PA, Sagulin GB, *et al.* Brånemark system and ITI Dental Implant System for treatment of mandibular edentulism. *Clin Oral Implants Res* 2001 **12:** 450–461.
30. Tawse-Smith A, Payne AG, Kumara R, *et al.* Early loading of unsplinted implants supporting mandibular overdentures using a one-stage operative procedure with two different implant systems: a 2-year report. *Clin Implant Dent Relat Res* 2002 **4:** 33–42.
31. Heydenrijk K, Raghoebar GM, Meijer HJ, *et al.* Clinical and radiologic evaluation of 2-stage IMZ implants placed in a single-stage procedure: 2-year results of a prospective comparative study. *Int J Oral Maxillofac Implants* 2003 **18:** 424–432.
32. Heydenrijk K, Raghoebar GM, Meijer HJ, *et al.* Two-stage IMZ implants and ITI implants inserted in a single-stage procedure. A prospective comparative study. *Clin Oral Implants Res* 2002 **13:** 371–380.
33. Meijer HJ, Heijdenrijk K, Raghoebar GM. Mucosal and radiographic aspects during the healing period of implants placed in a one-stage procedure. *Int J Prosthodont* 2003 **16:** 397–402.
34. Jones JD, Lupori J, Van Sickels JE, *et*

al. A 5-year comparison of hydroxyapatite-coated titanium plasma-sprayed and titanium plasma-sprayed cylinder dental implants. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 1999 **87:** 649–652.
35. Jones JD, Saigusa M, Van Sickels JE, *et al.* Clinical evaluation of hydroxyapatite-coated titanium plasma-sprayed and titanium plasma-sprayed cylinder dental implants. A preliminary report. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 1997 **84:** 137–141.
36. Mau J, Behneke A, Behneke N, *et al.* Randomized multicenter comparison of two coatings of intramobile cylinder implants in 313 partially edentulous mandibles followed up for 5 years. *Clin Oral Implants Res* 2002 **13:** 477–487.
37. Rocci A, Martignoni M, Gottlow J. Immediate loading of Branemark System TiUnite and machined-surface implants in the posterior mandible: a randomized open-ended clinical trial. *Clin Implant Dent Relat Res* 2003 **5 Suppl 1:** 57–63.
38. Åstrand P, Engquist B, Anzen B, *et al.* Nonsubmerged and submerged implants in the treatment of partially edentulous maxilla. *Clin Implant Dent Related Res* 2002 **4:** 115–127.
39. Geurs NC, Jeffcoat RL, McGlumphy EA, *et al.* Influence of implant geometry and surface characteristics on progressive osseointegration. *Int J Oral Maxillofac Implants* 2002 **17:** 811–815.
40. Jeffcoat MK, McGlumphy EA, Reddy MS, *et al.* A comparison of hydroxyapatite (HA) -coated threaded, HA-coated cylindric, and titanium threaded endosseous dental implants. *Int J Oral Maxillofac Implants* 2003 **18:** 406–410.
41. Orenstein IH, Tarnow DP, Morris HF, *et al.* Factors affecting implant mobility at placement and integration of mobile implants at uncovering. *J Periodontol* 1998 **69:** 1404–1412.
42. Truhlar RS, Farish SE, Scheitler LE, *et al.* Bone quality and implant design-related outcomes through stage II surgical uncovering of Spectra-System root form implants. *J Oral Maxillofac Surg* 1997 **55 (12 Suppl 5):** 46–54.
43. Ochi S, Morris HF, Winkler S. The influence of implant type, material, coating, diameter, and length on periotest values at second-stage surgery: DICRG interim report no. 4. Dental Implant Clinical Research Group. *Implant Dent* 1994 **3:** 159–162.
44. van Steenberghe D, De Mars G, Quirynen M, *et al.* A prospective split-mouth comparative study of two screw-shaped self-tapping pure titanium implant systems. *Clin Oral Implants Res* 2000 **11:** 202–209.
45. Friberg B, Jisander S, Widmark G, *et al.* One-year prospective three-center study comparing the outcome of a 'soft bone implant' (prototype Mk IV) and the standard Branemark implant. *Clin Implant Dent Relat Res* 2003 **5:** 71–77.
46. Gotfredsen K, Karlsson U. A prospective 5-year study of fixed partial prostheses supported by implants with machined and TiO_2-blasted surface. *J Prosthodont* 2001 **10:** 2–7.
47. Karlsson U, Gotfredsen K, Olsson C. A 2-year report on maxillary and mandibular fixed partial dentures supported by Astra Tech dental implants. A comparison of 2 implants with different surface textures. *Clin Oral Implants Res* 1998 **9:** 235–242.
48. Khang W, Feldman S, Hawley CE, *et al.* A Multi-Center Study Comparing Dual Acid-Etched and Machined-Surfaced Implants in Various Bone Qualities. *J Periodontol* 2001 **72:** 1384–1390.
49. Becker W, Becker BE, Ricci A, *et al.* A prospective multicenter clinical trial comparing one- and two-stage titanium screw-shaped fixtures with one-stage plasma-sprayed solid-screw fixtures. *Clin Implant Dent Relat Res* 2000 **2:** 159–165.
50. Chiapasco M, Gatti C. Implant-retained mandibular overdentures with immediate loading: a 3- to 8-year prospective study on 328 implants. *Clin Implant Dent Relat Res* 2003 **5:** 29–38.
51. Pinholt EM. Branemark and ITI dental implants in the human bone-grafted maxilla: a comparative evaluation. *Clin Oral Implants Res* 2003 **14:** 584–592.
52. Røynesdal AK, Ambjørnsen E, Haanes HR. A comparison of 3 different endosseous nonsubmerged implants in edentulous mandibles: A clinical report. *Int J Oral Maxillofac Implants* 1999 **14:** 543–548.
53. Røynesdal AK, Ambjornsen E, Støvne S, *et al.* A comparative clinical study of three different endosseous implants in edentulous mandibles. *Int J Oral Maxillofac Implants* 1998 **13:** 500–505.
54. Friberg B, Gröndahl K, Lekholm U. A new self-tapping Brånemark system implant: Clinical and radiographic evaluation. *Int J Oral Maxillofac Implants* 1992 **7:** 80–85.
55. Olsson M, Friberg B, Nilson H, *et al.* MKII – a modified self-tapping Brånemark system implant: 3-year results of a controlled prospective pilot study. *Int J Oral Maxillofac Implants* 1995 **10:** 15–21.
56. Friberg B, Nilson H, Olsson M, *et al.* Mk II: the self-tapping Brånemark system implant: 5-year results of a prospective 3-center study. *Clin Oral Implants Res* 1997 **8:** 279–285.
57. De Bruyn H, Collaert B, Linden U, *et al.* A comparative study of the clinical efficacy of Screw Vent implants versus Branemark fixtures, installed in a periodontal clinic. *Clin Oral Implants Res* 1992 **3:** 32–41.
58. Gómez-Roman G, Schulte W, Seiler M, *et al.* Implantationen im zahnlosen Unterkiefer Ergebnisse mit unterschiedlichen Implantatsystemen. *Z Zahnärztl Implantol* 1998 **14:** 8–16.
59. Ellegaard B, Baelum V, Karring T. Implant therapy in periodontally compromised patients. *Clin Oral Implants Res* 1997 **8:** 180–188.
60. Ellegaard B, Kølsen-Petersen J, Baelum V. Implant therapy involving maxillary sinus lift in periodontally compromised patients. *Clin Oral Implants Res* 1997 **8:** 305–315.
61. Graf HL, Geu B, Knöfler W, *et al.* Klinisches Verhalten des ZL-duraplant-Implantatsystems mit Ticer Oberfläche. Mitteilung 2: Zustandsbeschreibende Parameter. *Z Zahnärtzl Implant* 2002 **18:** 1–8.
62. Puchades-Roman L, Palmer RM, Palmer PJ, *et al.* A clinical, radiographic, and microbiologic comparison of Astra Tech and Brånemark single tooth implants. *Clin Implant Dent Relat Res* 2000 **2:** 78–84.
63. Krausse A, Forster J, Gerds T, *et al.* Implantologische und prothetische Erfolgsraten von Hybridprothesen zweier verschiedener Implantatsysteme. *Dtsch Zahnärztl Z* 2001 **56:** 680–683.
64. Noack N, Willer J, Hoffmann J. Long-term results after placement of dental implants: longitudinal study of 1,964 implants over 16 years. *Int J Oral Maxillofac Implants* 1999 **14:** 748–755.
65. Scurria MS, Morgan ZV 4th, Guckes AD, *et al.* Prognostic variables associated with implant failure: a retrospective effectiveness study. *Int J Oral Maxillofac Implants* 1998 **13:** 400–406.
66. Spiekermann H, Jansen VK, Richter EJ. A 10-year follow-up study of IMZ and TPS implants in the edentulous mandible using bar-retained overdentures. *Int J Oral Maxillofac Implants* 1995 **10:** 231–243.
67. Valentini P, Abensur DJ. Maxillary sinus grafting with anorganic bovine bone: a clinical report of long-term results. *Int J Oral Maxillofac Implants* 2003 **18:** 556–560.

68. Bianco G, Di Raimondo R, Luongo G, *et al*. Osseointegrated implant for single-tooth replacement: a retrospective multicenter study on routine use in private practice. *Clin Implant Dent Relat Res* 2000 **2:** 152–158.
69. Carr AB, Choi YG, Eckert SE, *et al*. Retrospective cohort study of the clinical performance of 1-stage dental implants. *Int J Oral Maxillofac Implants* 2003 **18:** 399–405.
70. Engquist B, Nilson H, Åstrand P. Single-tooth replacement by osseointegrated Brånemark system implants. A retrospective study of 82 implants. *Clin Oral Implants Res* 1995 **6:** 238–245.
71. Ferrigno N, Laureti M, Fanali S, *et al*. A long-term follow-up study of non-submerged ITI implants in the treatment of totally edentulous jaws. Part I: Ten-year life table analysis of a prospective multicenter study with 1286 implants. *Clin Oral Implants Res* 2002 **13:** 260–273.
72. Lentke A, Dahm G, Kerschbaum T, *et al*. Langzeitergebnisse von Brånemark-Implantaten in der Kölner Universitätszahnklinik. *Dtsch Zahnärztl Z* 2003 **58:** 88–93.
73. Malevez C, Hermans M, Daelemans P. Marginal bone levels at Brånemark system implants used for single tooth restoration. The influence of implant design and anatomical region. *Clin Oral Implants Res* 1996 **7:** 162–169.
74. Naert I, Koutsikakis G, Duyck J, *et al*. Biologic outcome of single-implant restorations as tooth replacements: a long-term follow-up study. *Clin Implant Dent Relat Res* 2000 **2:** 209–218.
75. Naert I, Duyck J, Hosny M, *et al*. Evaluation of factors influencing the marginal bone stability around implants in the treatment of partial edentulism. *Clin Implant Dent Relat Res* 2001 **3:** 30–38.
76. Naert IE, Koutsikakis G, Duyck JA, *et al*. Biologic outcome of implant-supported restorations in the treatment of partial edentulism. Part I: A longitudinal clinical evaluation. *Clin Oral Implants Res* 2002 **13:** 381–389.
77. Naert IE, Koutsikakis G, Quirynen M, *et al*. Biologic outcome of implant-supported restorations in the treatment of partial edentulism. Part 2: A longitudinal radiographic evaluation. *Clin Oral Implants Res* 2002 **13:** 390–395.
78. Quirynen M, Naert I, van Steenberghe D. Fixture design and overload influence marginal bone loss and fixture success in the Brånemark system. *Clin Oral Implants Res* 1992 **3:** 104–111.
79. Raghoebar GM, Friberg B, Grunert I, *et al*. 3-year prospective multicenter study on one-stage implant surgery and early loading in the edentulous mandible. *Clin Implant Dent Relat Res* 2003 **5:** 39–46.
80. Romeo E, Chiapasco M, Ghisolfi M, *et al*. Long-term clinical effectiveness of oral implants in the treatment of partial edentulism. Seven-year life table analysis of a prospective study with ITI dental implants system used for single-tooth restorations. *Clin Oral Implants Res* 2002 **13:** 133–143.
81. Wheeler S. Use of the Frialit-2 Implant System in private practice: a clinical report. *Int J Oral Maxillofac Implants* 2003 **18:** 552–555.
82. Chuang SK, Wei LJ, Douglass CW, *et al*. Risk factors for dental implant failure: a strategy for the analysis of clustered failure-time observations. *J Dent Res* 2002 **81:** 572–577.
83. Weyant RJ, Burt BA. An assessment of survival rates and within-patient clustering of failures for endosseous oral implants. *J Dent Res* 1993 **72:** 2–8.
84. Davarpanah M, Martinez H, Etienne D, *et al*. A prospective multicenter evaluation of 1,583 3i implants: 1- to 5-year data. *Int J Oral Maxillofac Implants* 2002 **17:** 820–828.
85. Gatti C, Chiapasco M. Immediate loading of Brånemark implants: a 24-month follow-up of a comparative prospective pilot study between mandibular overdentures supported by conical transmucosal and standard MKII implants. *Clin Implant Dent Related Res* 2002 **4:** 190–199.
86. Andersson B, Taylor A, Lang BR, *et al*. Alumina ceramic implant abutments used for single-tooth replacement: a prospective 1- to 3-year multicenter study. *Int J Prosthodont* 2001 **14:** 432–438.
87. Barclay CW, Last KS, Williams R. The clinical assessment of a ceramic-coated transmucosal dental implant collar. *Int J Prosthodont* 1996 **9:** 466–472.
88. Bollen CML, Papaioanno W, Van Eldere J, *et al*. The influence of abutment surface roughness on plaque accumulation and peri-implant mucositis. *Clin Oral Implants Res* 1996 **7:** 201–211.
89. Quirynen M, Bollen CM, Papaioannou W, *et al*. The influence of titanium abutment surface roughness on plaque accumulation and gingivitis: short-term observations. *Int J Oral Maxillofac Implants* 1996 **11:** 169–178.
90. McGlumphy EA, Peterson LJ, Larsen PE, *et al*. Prospective study of 429 hydroxyapatite-coated cylindric omniloc implants placed in 121 patients. *Int J Oral Maxillofac Implants* 2003 **18:** 82–92.
91. Behr M, Lang R, Leibrock A, *et al*. Complication rate with prosthodontic reconstructions on ITI and IMZ dental implants. *Clin Oral Implants Res* 1998 **9:** 51–58.
92. Bambini F, Muzio LL, Procaccini. Retrospective analysis of the influence of abutment structure design on the success of implant unit: a 3-year controlled follow up study. *Clin Oral Implants Res* 2001 **12:** 319–324.
93. Eckert SE, Wollan PC. Retrospective review of 1170 endosseous implants placed in partially edentulous jaws. *J Prosthet Dent* 1998 **79:** 415–421.
94. Scholander S. A retrospective evaluation of 259 single-tooth replacements by the use of Brånemark system implants. *Int J Prosthodont* 1999 **12:** 483–491.
95. Davarpanah M, Martinez H, Tecucianu JF, *et al*. The self-tapping and ICE 3i implants: a prospective 3-year multicenter evaluation. *Int J Oral Maxillofac Implants* 2001 **16:** 52–60.
96. Pihakari A, Nevalainen J, Hirvonen A, *et al*. The 2000 Dental Implant Yearbook. Helsinki: National Agency for Medicines 2001. [cited 2003 Jun 5] Available from: URL: http://www.nam.fi/uploads/julkaisut/78019_Dental_Implant.pdf
97. d'Hoedt B, Schulte W. A comparative study of results with various endosseous implant systems. *Int J Oral Maxillofac Implants* 1989 **4:** 95–105.
98. Eckert SE, Meraw SJ, Cal E, *et al*. Analysis of incidence and associated factors with fractured implants: a retrospective study. *Int J Oral Maxillofac Implants* 2000 **15:** 662–667.
99. Bahat O. Brånemark system implants in the posterior maxilla: clinical study of 660 implants followed for 5 to 12 years. *Int J Oral Maxillofac Implants* 2000 **15:** 646–653.
100. Balshi TJ. An analysis and management of fractured implants: a clinical report. *Int J Oral Maxillofac Implants* 1996 **11:** 660–666.
101. Berglundh T, Persson L, Klinge B. A systematic review of the incidence of biological and technical complications in implant dentistry reported in prospective longitudinal studies of at least 5 years. *J Clin Periodontol* 2002 **29 (Supplement 3):** 197–212.
102. Anderson JD. The need for criteria on reporting treatment outcomes. *J Prosthet Dent* 1998 **79:** 49–55.
103. Sennerby L, Roos J. Surgical determi-

nants of clinical success of osseointegrated oral implants: a review of the literature. *Int J Prosthodont* 1998 **11:** 408–420.
104. Weng D, Jacobson Z, Tarnow D, *et al.* A prospective multicenter clinical trial of 3i machined-surface implants: results after 6 years of follow-up. *Int J Oral Maxillofac Implants* 2003 **18:** 417–423.
105. Davarpanah M, Martinez H, Kebir M, *et al.* Wide-diameter implants: new concepts. *Int J Periodontics Restorative Dent* 2001 **21:**149–159
106. Friberg B, Ekestubbe A, Sennerby L. Clinical outcome of Branemark System implants of various diameters: a retrospective study. *Int J Oral Maxillofac Implants* 2002 **17:** 671–677.
107. Aparicio C, Orozco P. Use of 5-mm-diameter implants: Periotest values related to a clinical and radiographic evaluation. *Clin Oral Implants Res* 1998 **9:** 398–406.
108. Ivanoff CJ, Grondahl K, Sennerby L, *et al.* Influence of variations in implant diameters: a 3- to 5-year retrospective clinical report. *Int J Oral Maxillofac Implants* 1999 **14:** 173–180.
109. Eckert SE, Meraw SJ, Weaver AL, *et al.* Early experience with Wide-Platform Mk II implants. Part I: Implant survival. Part II: Evaluation of risk factors involving implant survival. *Int J Oral Maxillofac Implants* 2001 **16:** 208–216.
110. Attard NJ, Zarb GA. Implant prosthodontic management of partially edentulous patients missing posterior teeth: The Toronto experience. *J Prosthet Dent* 2003 **89:** 352–359.
111. Green NT, Machtei EE, Horwitz J, *et al.* Fracture of dental implants: literature review and report of a case. *Implant Dent* 2002 **11:** 137–143.
112. Benn DK. Estimating the validity of radiographic measurements of marginal bone height changes around osseointegrated implants. *Implant Dent* 1992 **1:** 79–83.
113. Oh TJ, Yoon J, Misch CE, *et al.* The causes of early implant bone loss: myth or science? *J Periodontol* 2002 **73:** 322–333.
114. Brunski JB, Puleo D, Nanci A. Biomaterials and biomechanics of oral and maxilloacal implants: current status and future directions. *Int J Oral Maxillofac Implants* 2000 **15:** 15–46.
115. Luterbacher S, Fourmousis I, Lang NP, *et al.* Fractured prosthetic abutments in osseointegrated implants: a technical complication to cope with. *Clin Oral Implants Res* 2000 **11:** 163–170.
116. Morgan MJ, James DF, Pilliar RM. Fractures of the implant component of an osseointegrated implant. *Int J Oral Maxillofac Implants* 1993 **8:** 409–414.
117. Piatelli A, Piatelli M, Scarano A, *et al.* Light and scanning electron microscopic report of four fractured implants. *Int J Oral Maxillofac Implants* 1998 **13:** 561–564.
118. Albrektsson T. Is surgical skills more important for clinical success than changes in implant hardware? *Clin Implant Dent Relat Res* 2001 **3:** 174–175.
119. Preiskel HW, Tsolka P. Treatment outcomes in implant therapy: the influence of surgical and prosthodontic experience. *Int J Prosthodont* 1995 **8:** 273–279.
120. Lambert PM, Morris HF, Ochi S. Positive effect of surgical experience with implants on second-stage implant survival. *J Oral Maxillofac Surg* 1997 **55(12 Suppl 5):** 12–18.
121. Salcetti JM, Moriarty JD, Cooper LF, Smith FW, Collins JG, Socransky SS, *et al.* The clinical, microbial, and host response characteristics of the failing implant. *Int J Oral Maxillofac Implants* 1997 **12:** 32–42.
122. Kronström M, Svensson B. Humoral immunity host factors in subjects with failing or successful titanium dental implants. *J Clin Periodontol* 2000 **27:** 875–882.
123. Hermann JS, Schoolfield JD, Schenk RK, Buser D, Cochran DL. Influence of the size of the microgap on crestal bone changes around titanium implants. A histometric evaluation of unloaded non-submerged implants in the canine mandible. *J Periodontol* 2001 **72:** 1372–1383.