

Implants and Components: Entering the New Millennium

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

Initially, the essential tenets for obtaining osseointegration dictated the atraumatic placement of a titanium screw into viable bone and a prolonged undisturbed, submerged healing period. By definition, this required a 2-stage surgical procedure. To comply, a coupling mechanism for implant placement and the eventual attachment of a transmucosal extension for restoration was explored. The initial coronal design selected was a 0.7-mm-tall external hexagon. At its inception, the design made perfect sense, because it permitted engagement of a torque transfer coupling device (fixture mount) during the surgical placement of the implant into threaded bone and the subsequent second-stage connection of the transmucosal extension that, when used in series, could effectively restore an edentulous arch.

As 20 years of osseointegration in clinical practice in North America have transpired, much has changed. The efficacy and predictability of osseointegrated implants are no longer issues.¹⁻⁷ During the initial years, research focused on refinements in surgical techniques and grafting procedures. Eventually, the emphasis shifted to a variety of mechanical and esthetic challenges that remained problematic and unresolved.⁸⁻¹⁰ During this period, the envelope of implant utilization dramatically expanded from the original complete edentulous application to fixed partial dentures, single-tooth

replacement, maxillofacial and a myriad of other applications, limited only by the ingenuity and skill of the clinician.¹¹⁻¹³ The external hexagonal design, ad modum Brånemark, originally intended as a coupling and rotational torque transfer mechanism, consequently evolved by necessity into a prosthetic indexing and antirotational mechanism.^{14,15} The expanded utilization of the hexagonal resulted in a number of significant clinical complications.^{8-11,16-22} To mitigate these problems, the external hexagonal, its transmucosal connections, and their retaining screws have undergone a number of modifications.²³ In 1992, English published an overview of the then-available external hexagonal implants, numbering 25 different implants, all having the standard Brånemark hex configuration.¹⁴ The external hex has since been modified and is now available in heights of 0.7, 0.9, 1.0, and 1.2 mm and with flat-to-flat widths of 2.0, 2.4, 2.7, 3.0, 3.3, and 3.4 mm, depending on the implant platform. The available number of hexagonal implants has more than doubled. The abutment-retaining screw has also been modified with respect to material, shank length, number of threads, diameter, length, thread design, and torque application (unpublished data, 1998).²³ Entirely new second- and third-generation interface coupling geometries have also been introduced into the implant milieu to overcome intrinsic hexagonal deficiencies.²⁴⁻²⁸ Concurrent with the evolution of the coupling geometry was the introduction of a variety of new implant body shapes, diameters, thread patterns, and surface topography.^{26,27,29-36}

Today, the clinician is overwhelmed with more than 90 root-form implants to select from in a variety of diameters, lengths, surfaces, platforms, interfaces, and body designs. Virtually every implant company manufactures a hex top, a proprietary interface, or both; "narrow," "standard," and "wide" diameter implant bodies; machined, textured, and hydroxyapatite (HA) and titanium plasma-spray (TPS) surface implants; and a variety of lengths and body shapes (Table 1). In the wide-diameter arena alone, there are 25 different offerings, 15 external hexagonal, and 10 other interfaces available in a number of configurations.

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Table 1 Summary of Manufacturers' Information

Company	Implant designs available	Implant designs and different diameters	Total no. implant bodies available	Body shapes available	Surfaces available	Diameters available	Lengths available	Different A/I interfaces	Platforms available	Abutments available	No. of tightening torques recommended	Tolerance in critical areas (µm)	Implant body metal	No. inspections / manf	ISO 9001 quality assurance	ISO 9002 quality assurance	EN 46001 dental products	EN 46002 medical products	ED93/42/EEC medical products	Good manufacturing process FDA
Nobel Biocare (Brånemark)	7	12	67	5	1	5	12	1	3	80	5	NIP	G1	NIP	Y	NA	Y	NA	Y	Y
Nobel Biocare (Steri-Oss)	13	47	210	3	3	7	6	5	7	316	1	NIP	G5A	NIP	Y	NA	Y	NA	Y	Y
Paragon Implant Co	13	35	140	5	6	7	4	2	5	> 45	3	± 6.4	G4, G23A	NIP	Y	NA	Y	NA	Y	Y
Implant Innovations Inc	6	36	> 160	4	4	6	7	5	5	94	3	± 3.8	G3, G4(1)*	17	Y	NA	Y	NA	Y	Y
Bicon Dental Implants	1	4	30	1	3	4	3	1	2	56	NA	NIP	G5A	3	Y	NA	Y	NA	Y	Y
Lifecore Biomedical	8	18	243	3	4	11	10	5	6	190	3	NIP	G3, G4, G5A	41	Y	NA	Y	NA	Y	Y
Friadent North America Inc	2	10	49	1	3	5	5	1	5	81	2	± 3.0	G3	12	Y	NA	Y	NA	Y	Y
Astra Tech	2	4	26	2	1	4	7	2	3	49	3	NIP	G4(1)*	4	Y	NA	Y	NA	Y	Y
Intec Corp	2	12	112	2	4	6	7	2	4	47	1	± 12.7	G3, G5A	4	NIP	NIP	NIP	NIP	Y	Y
Altiiva	1	2	8	1	1	2	4	0	2	0	NA	± 50.8		4	NIP	NIP	NIP	NIP	Y	Y
Osteo-Implant Corp	1	4	17	1	1	4	6	1	3	7	1	± 5.1	G3	15	NIP	NIP	NIP	NIP	Y	Y
Innova Corp	1	3	13	1	1	3	4	3	4	87	2	± 12.7	G5A	12	Y	NA	Y	NA	Y	Y
Bio-Lok International	8	34	130	4	3	9	5	4	4	144	3	± 7.6	G5A	8	Y	NA	Y	NA	Y	Y
Biomedical Implant Technologies	1	2	12	1	1	2	6	1	1	0	NA	± 101.6	G2	10	N	N	N	N	Y	Y
Basic Dental Implant Systems	1	3	8	1	1	3	3	1	1	3	NA	± 12.7	G4	6	NIP	NIP	NIP	NIP	Y	Y
Impladent Ltd	2	4	8	1	1	2	4	1	2	7	NA	± 5.1	G5A	29	Y	NA	Y	NA	Y	Y
Sterngold	7	21	94	2	3	6	5	1	3	78	3	± 12.7	G3	8	NIP	NIP	NIP	NIP	Y	Y
The Straumann Company	7	10	56	2	2	4	10	4	3	17	3	NIP	G4	NIP	Y	NA	Y	NA	Y	Y
O" Company	3	5	45	3	2	2	5	1	2	32	3	± 12.7	G4	5	NIP	NIP	NIP	NIP	Y	Y
Sulzer Calcitek	7	23	80	4	4	4	5	3	3	169	2	± 12.7	G5A	19	Y	NA	Y	NA	Y	Y
Biohorizon Implant Systems Inc	4	6	12	4	3	3	5	1	3	70	2	± 5.1	G5A	8	Y	NA	Y	NA	Y	Y
Sargon Enterprises Inc	1	1	3	1	1	1	3	1	1	9	1	NIP	G5A	NIP	Y	NA	Y	NA	Y	Y
Total	98	296	1363	52	53	100	126	46	72	1536										

Data obtained from a questionnaire, company catalogs, follow-up phone calls, e-mail, and fax to manufacturers to review data before publication. Every effort was made to be as accurate as possible. It was not possible to validate data provided by company sources.

*Materials used are G3 or G4 commercially pure titanium selected to have chemical purity equal to or better than G1.
NIP = no information provided; NA = not applicable.

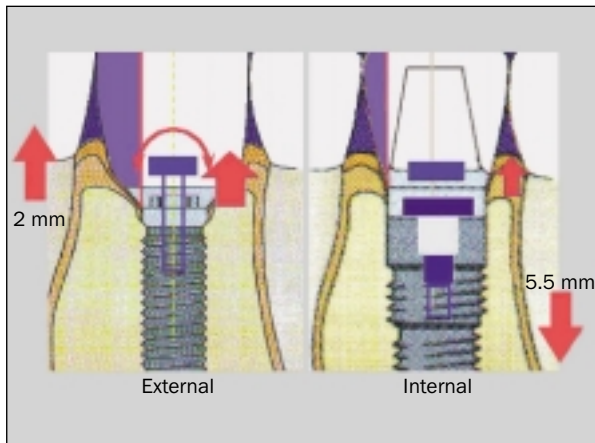


Fig 1 Implant interface connections are generally distinguished by a coupling that is superior (external) or inferior (internal) to the coronal surface of the implant. Typical external engagement that extends 1 to 2 mm above the coronal area of the implant and a contrasting internal engagement that extends 5.5 mm into the body of the implant

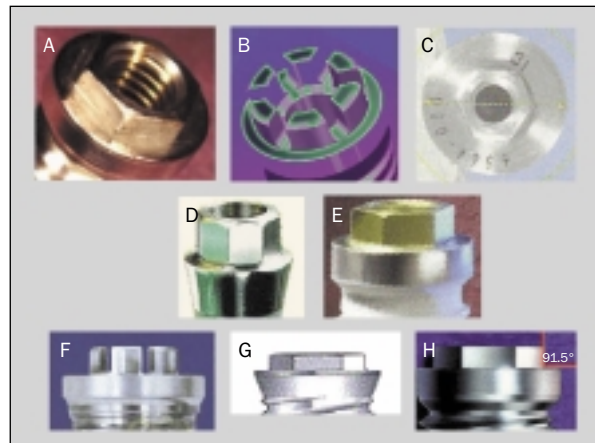


Fig 2 Representative external connections. A = 0.7-mm standard hexagonal, B = 1-mm spline on a standard platform, C = 0.7-mm hexagonal on a wide-diameter platform, D = 1-mm octagon on a narrow platform, E = 1-mm hex on a narrow platform, F = 1-mm spline on a wide platform, G = 1-mm hex on a wide platform, H = 0.7-mm tapered hex.

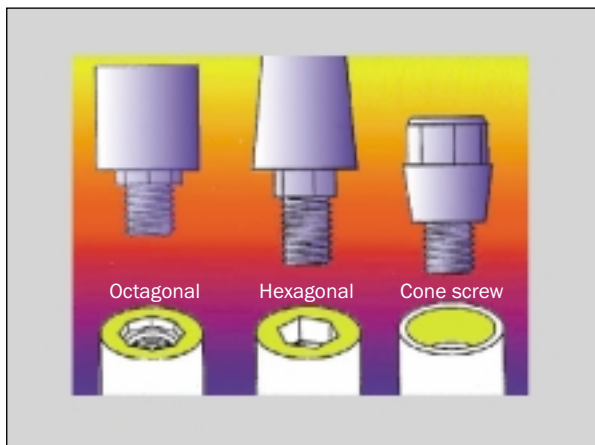


Fig 3 Internal nonrotational features: octagonal, hexagonal, and cone screw.

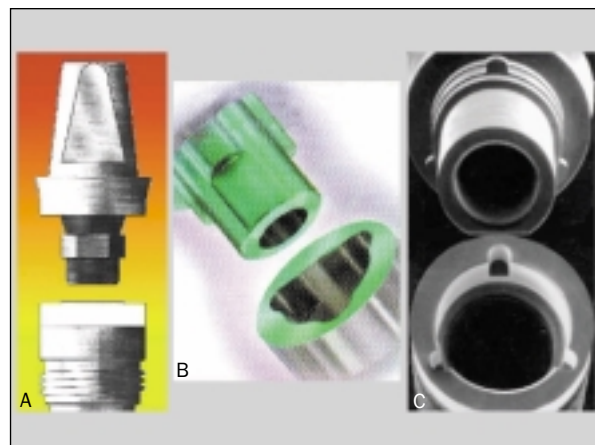


Fig 4 Internal nonrotational features: cylinder hex (A), cam tube (B), and cam cylinder (C).

IMPLANT CLASSIFICATION

The extensive variety of implants available today can be categorized and classified in a number of different ways. The most logical differentiation and distinctions are based on the implant/abutment interface, the body shape, and the implant-to-bone surface.

Implant/Abutment Interface

The implant/abutment interface connection, by convention, is generally described as an internal or external connection (Fig 1). The distinctive factor that separates the 2 types is the presence or absence of a geometric feature that extends above the coronal surface of the implant (Figs 2 to 4). The connection can

be further characterized as a slip-fit joint, where a slight space exists between the mating parts, and the connection is passive, or as a friction-fit joint, where no space exists between the mating components and the parts are literally forced together. The mating surfaces are further characterized as being a butt joint, which consists of 2 right-angle flat surfaces contacting, or a bevel joint, where the surfaces are angled either internally or externally (Fig 5). The joined surfaces may also incorporate a rotational resistance and indexing feature and/or lateral stabilizing geometry. This geometry is further described as octagonal, hexagonal, cone screw, cone hex, cylinder hex, spline, cam, cam tube, and pin/slot. Representative geometries are illustrated in Figs 2 to 4 and 6 to 11.

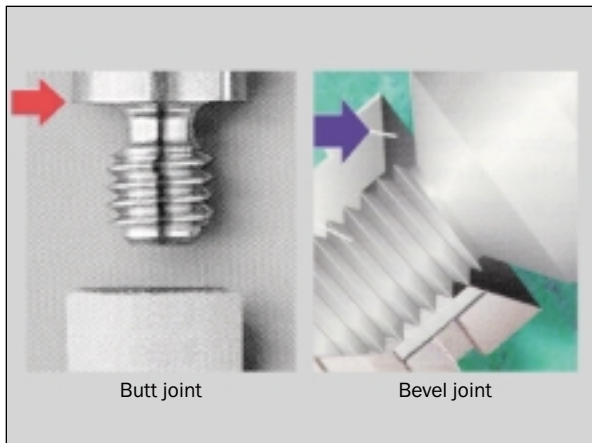


Fig 5 One-piece internal connections are characterized as a butt joint (flat surfaces) or bevel joint (angular surfaces).

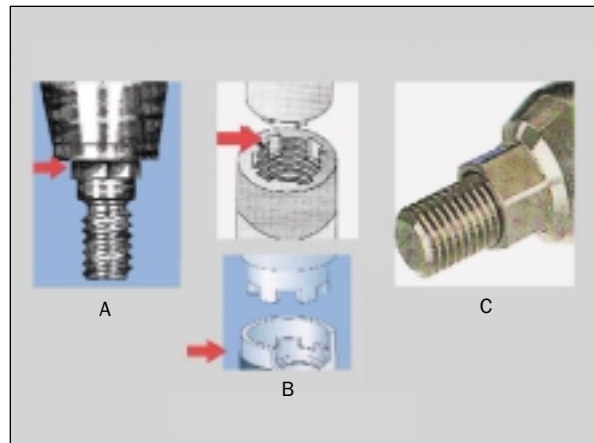


Fig 6 Examples of slip-fit, 2-piece antirotational internal connections: octagonal (A), internal spline (B), and internal hexagonal couplings (C).

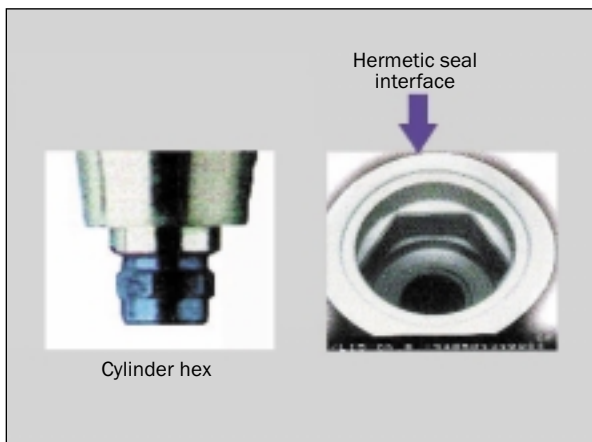


Fig 7 Example of slip-fit, 2-piece, threaded antirotational cylinder hex with hermetic seal interface.



Fig 8 Examples of slip-fit, 2-piece, non-antirotational, resilient and nonresilient internal connection.

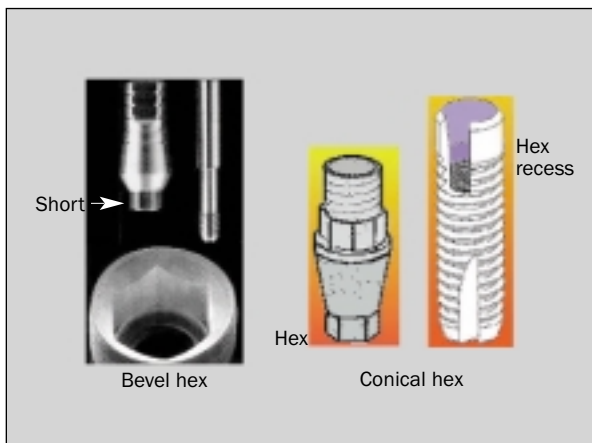


Fig 9 Examples of slip-fit, 2-piece, threaded antirotational connections: bevel hexagonal and a conical hexagonal interface.

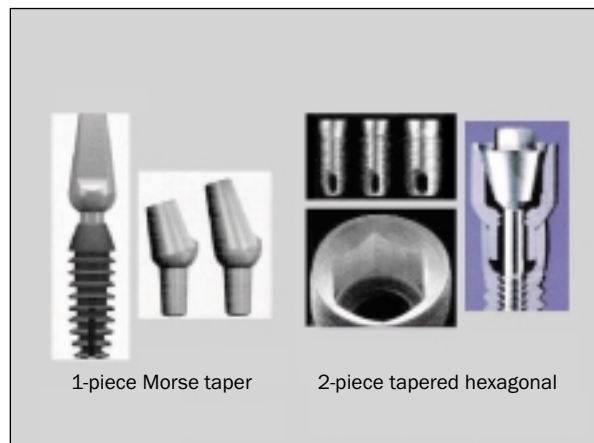


Fig 10 Friction-fit 1- and 2-piece internal connections: 1-piece Morse taper with frictional antirotation, and 2-piece tapered hexagonal that incorporates a frictional wedging effect and a retention screw.

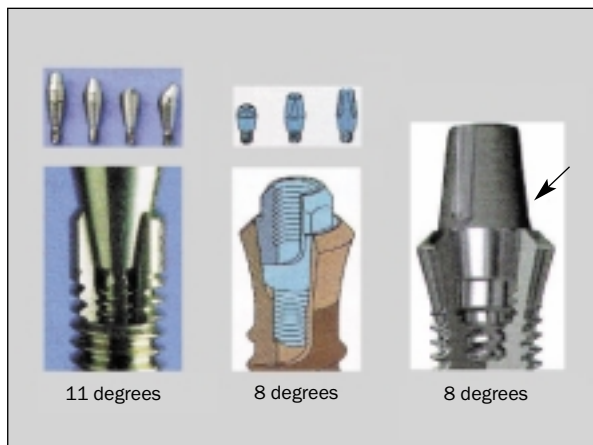


Fig 11 Examples of friction-fit, 1-piece cone screws that depend on wall engagement for frictional antirotation. The 8 degree cone screw (*center*) illustrates an “octa” abutment with a corresponding gold cylinder that engages the external bevel for a screw-retained restoration. The other configuration (*arrow*) is a 1-piece straight abutment post for a cement-retained restoration.

Body Geometry

The body geometry of the endosteal implant is characteristically cylindrical in shape. Initially 3 basic shapes were available: a threaded screw (ad modum Brånemark, Nobel Biocare, Göteborg, Sweden); a press-fit cylinder (ad modum IMZ, Interpore International, Irvine, CA); and a hollow basket cylinder (ad modum ITI, ITI-Straumann, Waldenburg, Switzerland) (Fig 12). The classical distinction was the presence or absence of threads and a solid or hollow cylinder. Development of the root-form implant over the past 20 years has resulted in a variety of different body geometries. The impetus for change was driven by the desire for surgical simplicity, greater predictability in poor-quality bone, immediate rather than delayed placement, improved stress distribution, better initial stability, and marketing distinction.

The classical geometric distinctions no longer apply, as a variety of features have been woven together into a variety of geometric shapes. Threaded screws can be characterized as straight, tapered, conical/tapered, ovoid, and expanding (Fig 13). Thread patterns have also been modified and now range from microthreads near the neck of the implant (Astra Tech, Lexington, MA); broad macrothreads on the mid-body (Biohorizons, Birmingham, AL; Steri-Oss, Nobel Biocare); a variety of altered pitch threads to induce self-tapping and bone compression (Implant Innovations, Palm Beach Gardens, FL; Nobel Biocare); and small limited-length threads for initial stability (Basic, Albuquerque, NM). Press-fit cylinders can be characterized as straight-walled, tapered, conical,

trapezoidal, and trapezoidal step (Fig 14). Additional distinctions can be made on the basis of steps, ledges, threads, vents, grooves, and the presence of an internal hollow recess. The implant body can also be distinguished by the presence or absence of a cervical collar, which can vary in width and angle, and the presence of a flared or straight neck (Fig 15).

Implant Surface and Coatings

The implant-to-bone surface has also undergone a number of different developments. The original offerings consisted of machined titanium (Brånemark), TPS (ITI group), and HA-coated (Sulzer Calcitek, Carlsbad, CA) implants. Progressively, the implant surface has been sintered and coated with spherical titanium powder; treated with leaching agents (nitric acid, hydrofluoric acid, hydrochloric acid, sulfuric acid); and air-abraded or particulate-blasted (aluminum oxide, tricalcium phosphate, or titanium dioxide of different sizes [25 to 250 μm]) either singularly or in combination to obtain a controlled surface texture to enhance cellular activity and bone-to-implant contact (BIC).^{37–40} Little question remains that a controlled surface texture enhances cell activity and increases BIC and the strength of integration.^{41–46}

Specific details of the processes are usually proprietary in nature. Manufacturers have marketed these surface conditions under a variety of designations such as Endopore (Innova Corp, Toronto, Ontario, Canada), TiOblast (Astra Tech), SLA (ITI), Osseotite (Implant Innovations), Osteo (Osteo Implant Corp, New Castle, PA), RBM (Lifecore, Chaska, MN), MTX (Sulzer Calcitek), THD (Steri-Oss), and others.^{43,47–49} Currently, this area is plagued with aggressive marketing to establish superiority and dominance. In contrast, the titanium plasma-sprayed surface process, originated by ITI and characterized by high-velocity molten drops of metal being welded to the implant body to a thickness of 0.3 to 0.4 mm, remains essentially unchanged. Its original intent was to obtain a greater surface area for bone attachment.²⁵ The results of ITI research on surface characteristics have changed its focus from TPS-coated implants to the sandblasted, acid-etched surface (SLA), which produces significantly greater BIC (55%) in comparison to TPS (37.5%).⁴²

Hydroxyapatite coatings are also applied to the implant bodies with plasma-spray technology.⁵⁰ Highly bioactive and osseointegrative, HA-coated implants demonstrated earlier and greater bone bonding.^{37,42,51,52} Although there are proprietary differences relative to crystallinity and amorphous content, the surface coating has generally remained the same, with one notable exception. Hydroxyapatite coating

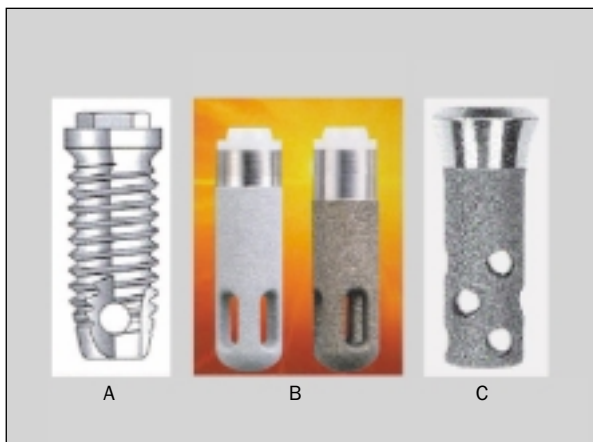


Fig 12 Classical body geometry represented by a threaded screw (A), cylinders (B), and a hollow basket (C).

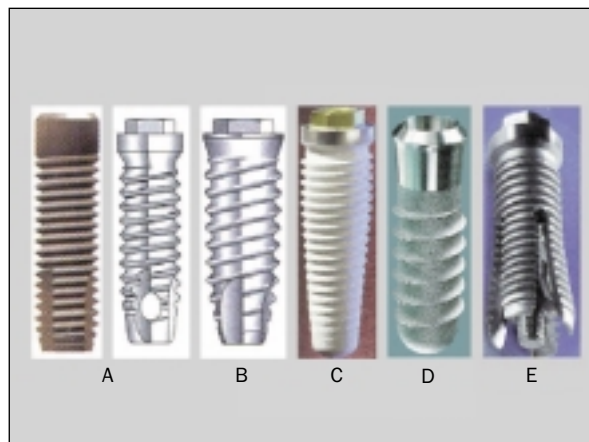


Fig 13 Threaded body geometry variations consisting of straight (A), tapered (B), conical (C), ovoid (D), and expanding bodies (E). Thread pitch, pattern, and depth vary considerably.

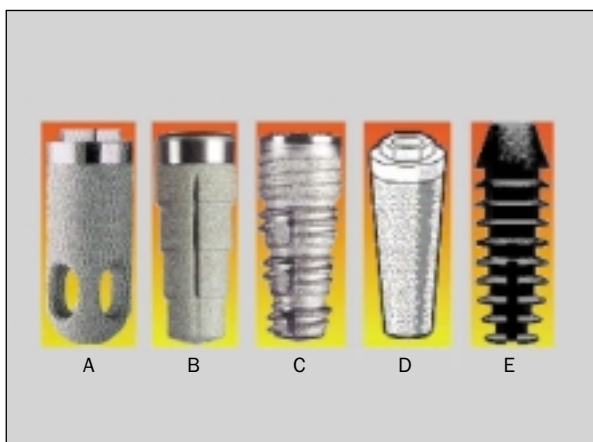


Fig 14 Press-fit body geometry variations, consisting of straight cylinder (A); trapezoid cylinder with steps (B), threads (C), or straight wall configuration (D); and a finned taper design (E).



Fig 15 Cervical geometry variations. 1 = Standard cervical collar with tapered neck, 2 = no collar, 3 = straight collar with no neck constriction, 4 = bevel cervical collars, 5 = reverse bevel with no cervical collar, 6 = tapered cervical collars with and without threads.

MP-1 (Sulzer Calcitek) uses a pressurized hydrothermal post-plasma-spray process that increases the crystalline HA content from 77% to 96%, with an amorphous content of 4%.^{53,54} Other commercial coatings range from 45% to 73% in crystalline HA content. The MP-1 coating exhibits significant decreased solubility over a wide range of pH.⁵³ Anecdotal reports of catastrophic failure rates and modes were responsible for a significant decline in HA-coated implant popularity in its early history. Evidence to the contrary has revitalized clinical use.⁵⁵⁻⁶⁰

An interesting recent innovation in surface technology is the combination of 2 or more different surfaces on the same implant body. The rationale is to achieve improved soft tissue response, stability, and attachment in cortical bone with a machined or etched coronal implant surface and better mechanical locking in medullar bone with a roughened, TPS, or HA surface in the middle to apical portion of the implant. One design incorporates 4 different surface textures on the same implant body (etched, grit-blasted, HA or TPS, and an etched apical tip).



Fig 16 Abutment geometry. 1 = Flat-top abutment, 2 = conical abutment, 3 = UCLA plastic and plastic with machined interface surface, 4 = UCLA variants Aurabase (Friadent) and AurAdapt (Nobel Biocare), 5 = straight cementable shoulderless abutment, 6 = single-tooth shoulder abutments CeraOne (Nobel Biocare) and STA (Implant Innovations) for cementable restorations.



Fig 17 Abutment geometry. 1 = Two-piece straight-shoulder abutments for cementable and set-screw-retained crowns (Steri-Oss and Friadent). Shoulders can be modified to tissue contour. 2 = Two-piece angled shoulder abutments with shoulders that can be modified according to need (Angled Esthetic Abutment, Steri-Oss; and MH-6, Friadent). 3 = Straight-shouldered 1-piece cementable abutment (Implant Innovations). 4 = Custom milling abutment (Friadent). 5 = CeraBase ceramic abutment with metal base (Friadent). 6 = CerAdapt ceramic direct-connection abutment (Nobel Biocare). 7 = Two-piece overdenture ball attachments.

THE ABUTMENT CONNECTION

Definitive abutment connections can be characterized in many different ways. The basic categories available are:

1. One- and 2-piece flat-top
2. One- and 2-piece conical shouldered
3. UCLA-type plastic castable
4. UCLA machined/plastic cast to cylinders
5. UCLA gold sleeve castable
6. One-piece fixed post
7. Two-piece fixed shoulder
8. Preangled fixed
9. Telescopic millable post
10. Ceramic
11. Single-tooth direct connection
12. One- and 2-piece overdenture abutments (Figs 16 and 17).

The initial connections were sleeves of various lengths that mated to the implant with connecting screws (abutment screws) or 1-piece extensions with flat or conical tops (Fig 16). The original focus was to restore the completely edentulous mouth, which required multiple implants and a transition zone through soft tissue that easily permitted the splinting of all the root analogs with a metal bar superstructure (fixed or removable) secured with smaller

prosthetic screws. The resulting restorations resembled pier-like structures that were highly functional but limited in esthetic appeal. The expanded utilization of implants resulted in a tremendous diversity and number of abutment connections to handle the ever-increasing range of clinical challenges.

The early transition from the completely edentulous arch to fixed partial denture (FPD) applications resulted in the development of 2-piece conical abutments that brought the coronal area ever closer to the implant interface and permitted changes in angulation.⁶¹ The advent of the UCLA connection eliminated the intermediate transmucosal connection completely and improved esthetics dramatically (Fig 16).^{62,63} The concept was modified to include an all-machined metal cast to cylinder, a machined interface with a plastic burnout extension, and all-plastic castable sleeves. Each is available with and without an antirotation engagement. Although a major advancement, the inevitable problem of a screw access channel persisted. This was especially problematic with angulation changes. The same direct-connection concept was extended further to include a machined hexagonal body with a low-profile shoulder (eg, CeraOne, Nobel Biocare; and STA, Implant Innovations) that would receive single-unit cemented restorations (Fig 16).⁶⁴⁻⁶⁶ This refinement eliminated the esthetically compromising abutment screw access channel and the vulnerable porcelain-to-metal

occlusal interface. Two sophisticated variations of the UCLA concept used to produce custom cast abutments are AurAdapt (Nobel Biocare) and Aurabase (Friadent, Irvine, CA). These permit replication of natural-tooth cervical profiles and can be used in esthetic areas having limited soft tissue height with virtually no facial metal collar (Fig 16).

Similarly, machined 1- and 2-piece straight and preangled cementable abutments became readily available. The driving forces were simplicity and esthetics. Initially rather crude with respect to cervical collar size and flare, they have been refined into very user- and tissue-friendly components that have integrated implant prosthodontics into the arena of conventional fixed prosthodontics. The full extension of this concept is the 2-piece cementable straight or angled abutment that permits axial correction and shoulder modification to conform to a given clinical situation. Refined examples of this design type are the Angled Esthetic Abutment (Steri-Oss) and MH-6 (Friadent) (Fig 17).

Additional demand for optimal single-tooth implant esthetics has led to perhaps the most exciting development in implant abutment design, the ceramic abutment.⁶⁷⁻⁷⁰ Three different designs are currently available. CerAdapt (Nobel Biocare) consists of an internally hexed high-strength aluminum oxide cylinder that is shaped and prepared with diamond tooling and copious water, quite similar to natural-tooth preparation (Fig 17). Ceramic behavior, however, is significantly more brittle and technique-sensitive. Specific handling requirements must be followed in every detail. The ceramic abutment is directly retained on the implant with an abutment screw at 32 Ncm, and an all-ceramic crown can then be cemented in place. Clinically, whenever ceramic and metal come into contact, the metal will most likely abrade and wear.⁷¹ The same is true for the contact of aluminum oxide with the titanium implant body and gold-alloy screws. The most problematic area is the possible rounding of the corners of the hexagonal during the fabrication process when seating and reseating of the abutment takes place.⁷² The CeraOne abutment (Nobel Biocare), mentioned previously, has prefabricated aluminum oxide caps that are used as a core for the production of an all-ceramic crown (Fig 16). The resulting restoration is luted with permanent cement onto the titanium abutment. This eliminates any ceramometal abrasion at the screw seat and implant interface but requires absolute confidence in long-term screw joint stability. Another approach in ceramic abutment technology is CeraBase (Friadent), which uses a metal screw seat and platform with a preable high-strength ceramic cylinder (Fig

17). A ceramic cylinder or pre-shaped abutment form is tooled with rotary instruments under a copious water supply to conform to the desired clinical form.⁷⁰ A conventional all-ceramic crown can then be luted to the ceramic abutment with a permanent cement, or the abutment itself can be used as a core for an all-ceramic crown that is screw-retained. In both instances, the ceramic abutment is bonded with resin cement onto the metal-retaining platform.

Removable implant-supported restoration components are primarily low-profile, 2-piece machined cast to or plastic sleeves for direct connection to the implant; 1- or 2-piece conical abutments; or 1- or 2-piece ball retention devices (Fig 17). The ball abutments are available in different vertical heights to accommodate tissue thickness and different diameters with accompanying retention caps. A few manufacturers also offer magnet retention and low-profile Zaag-type attachments (Zest Anchors Inc, Escondido, CA).

A CRITICAL LOOK AT THE IMPLANT/ABUTMENT INTERFACE

Currently, there are some 20 different implant/abutment interface geometric variations available. The geometry is important because it is one of the primary determinants of joint strength, joint stability, and locational and rotational stability. It is critical to and synonymous with prosthetic stability. With few exceptions, most of the long-term clinical data on performance reported in the literature involve the external hexagonal. This is primarily the result of its extensive use, the broad number of prescribed clinical applications, the level of complications reported, and the resultant efforts to find solutions. In its original context of utilization, the hexagonal was used to restore the completely edentulous arch. All the implants were joined together with a rigid metal superstructure, and the external hexagonal and simple butt and bevel joints performed quite well.^{1,2} Long-term stability simply required an accurately fitting framework and adherence to basic mechanical principles. In more complex, in-line, partially edentulous, and single-tooth applications, the interface and its connecting screw are exposed to more rigorous load applications.^{73,74} The retaining screw is no longer shielded from stress and is subject to lateral bending loads, tipping, and elongation, which result in joint opening and screw loosening.⁷⁵⁻⁷⁸ Short, narrow external geometry is particularly vulnerable because of the limited engagement of its external member and the presence of a short fulcrum point (small platform) when tipping forces are applied.^{79,80}

This deficiency was originally noted by Brånemark, who recommended that the external hex connection be a minimum of 1.2 mm in height to provide both lateral and rotational stability, particularly in single-tooth applications.⁸¹ The original 0.7-mm design and its countless clones, however, remained unchanged until recently, when wider and taller hexagonals were introduced. Hexagonal screw joint complications, consisting primarily of screw loosening, were reported in the literature and ranged from 6% to 48%.^{8-11,16-22,82,83} The consequences of maintaining an unstable geometry in practice can be significant. A 22-month follow-up on external hex implant prostheses in a private prosthodontic practice reported the incidence of loose screws in fixed and removable prostheses at 27% and 32%, respectively.⁸⁴ The necessary adjustment and repairs were generally done at the prosthodontist's expense, with a mean office adjustment cost per visit of \$106. Only 16% were billable to the patient.

During the past 10 years, all major manufacturers have recommended specific torque application to abutment screws and sell system-specific torque wrenches. Although controlled torque application and altered screw designs have significantly improved performance, they have not eliminated the joint problem entirely. Haas et al reported on 76 single-hex implant/abutment interfaces with high torque and improved screw configuration and observed 16% loose screws during a mean observation time of 22.8 months.⁸⁵ In a 5-year follow-up report, the same authors reported a 9% occurrence of abutment screw loosening during the last 3 years. Subsequent modification of hex height and width, in concert with an increased loading platform, have further improved performance in laboratory tests (unpublished data, 1997).⁸⁶ However, several factors still remain unresolved. Clinically, it is often difficult, even for the experienced operator, to seat components on the hex easily and with confidence, especially in the posterior part of the mouth. From a clinical perspective, perhaps the most vexing problem is the rotational misfit that occurs when an abutment is fitted to the working cast analog and then transferred to the implant in the mouth to receive a cemented FPD framework.⁸⁷ Minute rotational changes at a single abutment location can result in misfit of the superstructure. This problem is compounded further in complex, multiple-implant-supported FPD at each transfer. In response, some manufacturers have made great efforts to improve the tolerances of the standard hex and the corresponding abutment recess.⁸⁸ The wider and taller hex configurations have reduced this problem, since they are easier to machine and generally have tighter tolerances (unpublished data, 1997). As

such, they have demonstrated reduced rotational misfit but have not completely eliminated it. However, 2 different design changes have essentially eliminated all rotation between the implant hex and the abutment. One consists of adding a 1.5% taper to the hex flat and a corresponding close-tolerance hexagonal abutment recess that is friction-fitted onto the hex (Swede-Vent TL, Paragon Implant Co, Encino, CA).⁸⁹ The other involves the addition of microstops in the corners of the abutment hexagonal that engage the corners of the implant hex (ZR Abutment, Implant Innovations Inc).⁹⁰

To overcome some of the inherent design limitations of the external hexagonal connection, a variety of alternative connections have been developed. The most notable are the cone screw, the cone hex, the internal octagonal, the internal hexagonal, the cylinder hex, the Morse taper, the spline, the internal spline, and the resilient connection. Of these, the internal octagonal connection (Omniloc, Sulzer Calcitek) and the resilient connection (IMZ) are no longer available. The octagonal design, because of its thin walls, 0.6-mm length, and a small diameter that presented a geometry profile similar to a circle, offered minimal rotational and lateral resistance during function. The IMZ resilient connection offered a polyoxymethylene insert that, theoretically, replicated the periodontal membrane and buffered implant loading (Fig 8). Chronic maintenance problems impacted popularity and forced a redesign utilizing a metal insert.^{91,92} Ownership transfers and conflicts over distribution rights effectively terminated North American sales.

Essentially 2 other external connections are available besides the hex. One is an external octagon, and the other consists of parallel key or splines (Fig 2). The external octagon is a unique 1-piece narrow-diameter (3.3-mm and 3.5-mm) implant (ITI Narrow Neck) designed for mandibular anterior use. The tall, well-toleranced octagonal extension allows for 45-degree rotation, very good lateral and rotational resistance, and good strength. The Spline implant connection (Sulzer Calcitek) consists of 6 external parallel keys (splines) alternating with 6 grooves. The abutment has a mirror-image design pattern that is engineered to fail before damaging the implant. Spline geometry comes in 2 designs and 3 platforms. The 4-mm and 5-mm platforms have the same geometry, are strong and mechanically stable, and demonstrate minimal rotational movement and screw loosening.²⁸ However, the spline geometry on the narrow 3.25-mm implant is quite different. Thinner, smaller splines, plus a narrow loading platform, result in a frail, vulnerable interface. No clinical reports have been published on the stability of this interface.

Internal interface designs offer a reduced vertical height platform for restorative components; distribution of lateral loading deep within the implant; a shielded abutment screw; long internal wall engagements that create a stiff, unified body that resists joint opening; wall engagement with the implant that buffers vibration; the potential for a microbial seal; extensive flexibility; and the ability to lower the restorative interface to the implant level esthetically.

The cone screw tapered connection originated with the ITI group in Switzerland (Fig 11).³⁴ The rationale was that an internal tapered connection would yield a mechanically sound, stable, self-locking interface. An additional innovation, first advocated with this implant design, was the elimination of submergence during osseointegration, resulting in a 1-stage surgical protocol.⁹³⁻⁹⁵ Although the connection is called a Morse taper, the mating angle between component parts is 8 degrees. A true Morse taper exists at 2 degrees and 4 degrees and has unique self-locking characteristics without threads. It is doubtful that the 8-degree connection would remain intact without its retaining screw component. However, the combination of the 2 stabilizing elements has resulted in a strong, stable, and predictable connection.³⁴

Conical connections require precise machining and tolerances, which for this manufacturer are consistent and excellent. Essentially 2 different abutments are available: the original short-profile "octa" abutment with a machined cast-to-coping that engages the external implant bevel and allows for screw-retained restorations, and a straight post that can be modified for cemented FPD applications. The joint configuration has no antirotational feature and depends entirely on the application of proper tightening torque and, most critically, the frictional resistance of its tapered walls. The long wall engagement does shield the screw and provides increased resistance to screw loosening. However, some clinical reports have reported screw loosening. A multicenter study of 174 implants reported that 8.7% of prosthetic screws and 3.7% of cone abutment screws were loose at 6 months.⁹⁶ Another study, with a mean observation time of 3.5 years, reported loose screws at 9.1% and screw fractures and abutment complications at 1.5%.⁹²

A similar cone screw connection with an 11-degree taper is available from Astra Tech (Fig 11). The abutment configuration is different in that it does not engage the external bevel on the implant and offers different length extensions with a 20-degree and 45-degree conical head. The original 11-degree cone design relied completely on screw and frictional resistance. Reported complications vary.

No screw failures or joint problems were reported by Arvidson et al over a 3-year period on 310 implants in mandibular prostheses.⁹⁷ In a subsequent investigation of 517 implants with a 5-year follow-up, Arvidson et al reported no prosthetic or abutment screw loosening, fracture, or complications.⁹⁸ Karisson et al reported a 2-year follow-up of 133 implants in the maxilla and mandible with fixed and removable prostheses with complications at 1 and 2 years. Four percent and 3% of prosthesis screws were loose, respectively; loose abutments totaled 2.3% and 0.75%, respectively; and abutment fractures were 1.5% during the first year only.⁹⁹ This geometry has been modified to a 2-piece abutment with an antirotational hex feature at the end of the cone (ST, Astra Tech) for single-implant applications (Fig 9). The abutment is secured in the implant with a screw. The long tapered-wall engagement provides excellent resistance to lateral loads, some frictional resistance, and a secure interface seal. Mechanical test values are very good, and clinical data support good stability.¹⁰⁰

With respect to strength characteristics between conical and external hex butt joints, the conical joint is approximately 60% stronger.¹⁰⁰ Conflicting evidence exists with respect to the cone screw requiring a higher loosening torque than was originally applied. Sutter et al have reported that the loosening torque required for ITI connections was greater (124%) than the original tightening (input) torque.³⁴ Other studies have shown that for both the 8-degree and 11-degree connections, the loosening torque is 80% to 85% of the original tightening torque (unpublished data, 1997).¹⁰¹

Several internal hexagonal configurations are available (Figs 6, 7, 9, and 10). This basic concept has evolved into a variety of unique and very different interfaces. The initial offering was a slip-fit connection with the male hex extending from the abutment, very similar to the previously described internal octagonal. It effectively reduced the vertical height of the restorative platform and made seating components easier. Subsequent changes by one manufacturer resulted in a longer hex with a 1-degree taper that provided an interference friction fit (ScrewVent TL, Paragon Implant Co) (Fig 10). In the narrow (3.5-mm) configuration, the internal lead in bevel, the sharp internal corners that receive the male hex, a thin implant wall, and the interference press-fit seating, in combination with inappropriate treatment planning and overload, can result in wall fracture. A 7-year prospective study of this design reports 65.2% and 43.5% success rates in the mandible and maxilla, respectively, and a mean bone loss of 2.9 mm.¹⁰² The authors note that "stress analysis . . . revealed that

maximum compressive stresses are concentrated within the cylindrical collar and upper $\frac{1}{2}$ of the implant body. This stress is transferred to . . . bone . . . this may be an explanation for . . . ongoing bone loss."^{102,103} In the 4.5-mm and 5.7-mm bodies, a horizontal shelf has been added immediately below the lead in bevel. This, along with increased wall thickness, has improved strength and fatigue resistance. The slip-fit, internal-cylinder hex interface is a unique internal design that extends 5 mm into the implant body (Frialit-2, Friadent) (Fig 7). The hexagonal is interposed between superior and inferior cylinders on the abutment connection. The hex provides rotational resistance and 60-degree indexing. The cylinders provide excellent lateral load resistance, resistance to joint opening, protection of the abutment screw, and very high strength values.¹⁰⁴ When the joint does fail, only the abutment fails, and the implant remains intact. The interface also has excellent tactile perception, and the abutment virtually seats itself. The interface has a circumferential groove to accept a silicone gasket that effectively reduces bacterial penetration into the joint (Hermetic Seal, Friadent).¹⁰⁵ Mechanical tests indicate good strength, minimal rotation, superior screw stability, and resistance to loosening, along with excellent machining tolerances.^{106,107} A wide variety of abutments are available, and they are exceptionally easy to seat. Currently available in 3.8-mm, 4.5-mm, 5.5-mm, and 6.5-mm platforms, the manufacturer is scheduled to release a narrow platform (3.3-mm or 3.5-mm) this year.

Two new internal designs, similar in concept yet quite different, have entered the market. Replace Select (Nobel Biocare) is a deep cam tube arrangement that has been transferred to a successful existing body design (Fig 4). The long tube insert offers excellent lateral stability, and the cam engagements provide convenient seating and indexing. The second entry, Camlog (Altatec Biotechnologies, Irvine, CA) is a cylinder cam that has been available in Europe for a short time (Fig 4). It also has a deep cylinder that engages the internal walls of the implant and is reported to be 60% stronger than external hex designs.¹⁰⁸ Three lateral cam projections provide indexing and antirotation. The Camlog implant body is a cylinder hybrid, with 6 widely spaced threads at the superior one-third of its body. Currently, no data are available from the manufacturers or in the literature on either design.

A true Morse tapered implant interface connection is available (Bicon, Boston, MA) without any threaded component (Fig 10). The abutment has a 1- to 2-degree tapered post that fits into a smooth mirror-image shaft within the implant. The abut-

ment is seated with a sharp blow on the long axis of the implant. It requires a dry, clean abutment post and implant shaft to secure the frictional resistance fit and provide optimal resistance to dislodgment. Without any indexing feature, it is not possible to transfer exact abutment location with consistency and repeatability. Modification of straight and angled abutments has to be completed intraorally, which is difficult in complex multi-implant FPD applications. The manufacturer's recommended method of removal for the intact abutment is to twist and turn with a forceps. Retrieval of a fractured abutment post and retrofitting a new abutment may therefore prove challenging. Although the connection has demonstrated stability during function, it lacks flexibility from a restorative perspective.

The general focus is clearly on deep internal joints, in which the screw takes little or no load and provides intimate contact with the implant walls to resist micromovement, resulting in a strong stable interface. The classic article by Mollersten et al clearly indicated the strength advantage of an internal connection.¹⁰⁴ To avoid joint failure, adherence to specific clinical, as well as mechanical, parameters is critical. With respect to hardware, optimal tolerance and fit, minimal rotational play, best physical properties, a predictable interface, and optimal torque application are mandatory. In the clinical arena, optimal implant distribution; load in line with implant axis; optimal number, diameter, and length of implants; elimination of cantilevers; optimal prosthesis fit; and occlusal load control are equally important.

ABUTMENT SCREW DESIGN

In a further effort to overcome problems with joint instability, the abutment screw has evolved to maximize preload and minimize loss of input torque to friction.²³ It currently consists of a pan (flat) head seat, long stem length, and 6 thread lengths (Fig 18). The increased stem length aids in attaining optimal elongation, and shorter thread lengths reduce friction.¹⁰⁹ When less input torque is lost to friction and heat, a higher preload is achieved.¹¹⁰ The single most significant factor that determines the bolting characteristics of the screw is the construction material, and manufacturers have made numerous changes in that regard. The friction resistance between the titanium of the implant threads and the titanium of the screw threads, resulting in part from "galling," a form of adhesive wear that occurs during the intimate sliding contact of 2 like materials, limits the preload characteristics of titanium screws.¹⁰⁹ Hence transition has been made to the gold-alloy screw.⁶⁶

Gold-alloy screws have a lower coefficient of friction, can be tightened more effectively to higher preloads, and will not stick to titanium. A gold-alloy screw can attain preloads of more than 890 N at approximately 75% of its yield strength, which is more than twice that attainable with a titanium-alloy screw (S. Hurson, personal communication, 1999). Current gold screw metallurgy varies between manufacturers, ranging in gold content from 64.1% to 2%, with yield strengths of 1,270 N to 1,380 N.¹¹¹ Proper handling of gold screws is a concern, as the screw threads are meant to deform upon tightening. It is therefore recommended that gold screw use be limited to the final clinical placement process.

In an effort to reduce frictional resistance even more, dry lubricant coatings have been applied to abutment screws. Most notable are TorqTite (Nobel Biocare) and Gold-Tite (Implant Innovations). TorqTite is a proprietary Teflon coating applied to titanium alloy screws, with a reported reduction of the frictional coefficient by 60% (S. Hurson, personal communication, 1999). The reported data indicate an effective increase in attainable preload for titanium alloy screws at a significantly lower cost than its gold-alloy counterpart. The Gold-Tite approach is to coat the standard gold-alloy screw with 0.76 μm of pure gold. With a tightening torque of 32 Ncm, the manufacturer reports a 24% increased preload for the coated screw.¹¹² Available data on the effectiveness of friction-reducing coatings is primarily manufacturer-based. Although theoretical calculations predict an increase in attainable preload, numerous tests on the preload of lubricated and unlubricated screws indicate that there may be no significant statistical difference.^{113,114} Another concern relates to the wear of the coated/plated screws after repeated tightening sequences. The effectiveness of this technology on screw joint stability has yet to be fully documented with independent research and in clinical trials.

WIDE- AND NARROW-DIAMETER IMPLANTS AND PLATFORMS

The origin of the wide-diameter implant can be traced to the hollow-basket designs of ITI and Ventplant (3M Health Care, Dental Products Division, St. Paul, MN).^{115,116} For threaded screws, it was intended as a rescue implant when the osteotomy site was oversized.³⁰ Since then, it has demonstrated numerous clinical advantages (unpublished data).¹¹⁷ It is especially appropriate in posterior areas requiring greater stability and resistance to masticatory

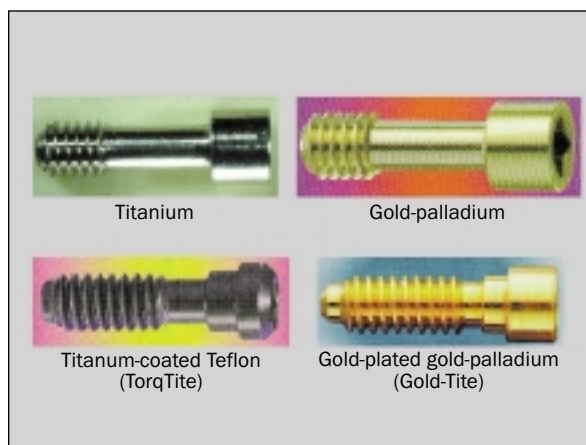


Fig 18 New screw designs: titanium (alloy) and gold-palladium alloy pan head screws with fewer threads and long shank for optimal elongation. Coated screws to reduce frictional resistance: titanium-coated Teflon screw (TorqTite, Steri-Oss) and gold-plated gold-palladium alloy screw (Gold-Tite, Implant Innovations).

loads.^{118,119} The typical designs are a straight or tapered screw, a trapezoidal cylinder, a step cylinder, or a hybrid cylindrical tapered screw.

The most frequently used threaded implants still range in diameter from 3 to 4 mm.¹²⁰ The typical 3.75-mm threaded screw implant has a 0.4-mm wall thickness. With crestal bone loss, it is vulnerable to fatigue fracture. Fracture rates for commercially pure grade 1 titanium (CPT1) 3.75-mm implants have been reported at 7%, 13%, and 16% over respective periods of 5, 10, and 15 years.² In contrast, 5-mm and 6-mm implants are 3 and 6 times stronger, and the risk of fracture is eliminated.³¹ Irrespective of physical properties, a wider body significantly increases the available surface for integration and lessens stress to the bone-implant interface (unpublished data). By virtue of its increased circumference, it also decreases off-axis load transfer, which is highest at the neck of the implant and the crest of the ridge.¹¹⁸ This reduces the potential for crestal overload, which is typically associated with bone loss. A wide platform also increases abutment stability by reducing the occlusal-table-to-loading-platform cantilever and the concomitant stress to the abutment screw.¹¹⁸ Regardless of the size of external hex engagement, wide-diameter implants perform exceptionally well in cyclic loading tests and demonstrate increased resistance to screw loosening (unpublished data). The wider loading platform also permits an emergence profile that correlates more closely to the natural tooth it replaces.¹¹⁷ Early clinical experience with wide-diameter threaded implants was guarded, as anecdotal reports of increased bone

loss surfaced. Although limited data appear in the literature, evolutionary changes in thread patterns and collar design and gentler and more fastidious surgical techniques have been recommended to overcome these initial difficulties.

With the advent of single-tooth replacement came the need for narrow-diameter implants for maxillary lateral incisors and mandibular incisors. The smallest-diameter external engagement implants available are 3.25-mm (hex) and 3.3-mm (octagon). Because of a reduced loading platform, the external male member has been modified in height to attain adequate lateral stability and strength. The 3.25-mm Spline is the only exception, having thinner and smaller keys. Internal engagements are more difficult to modify to a narrow platform because of inherent wall thickness limitations and fracture potential. The narrowest internal engagement implant currently available is the 3.5-mm Astra implant. In 2 prospective studies, one with 2-year and the other with 5-year follow-up, the implant success rates were 97.7% and 98.7%, respectively, with minimal prosthetic complications.^{121,122} Interface bending strength of the small-diameter cone screw connection was 40% greater than a 3.75-mm hex top, indicating that this diameter and interface can be used with confidence.¹⁰⁰ Little published data are available on any other narrow-diameter connections.

THREAD DESIGN

The original Brånemark screw, introduced in 1965, had a V-shaped thread pattern as a means of placement into a threaded osteotomy.^{1,2} The design was modified in 1983 as a self-tapping implant for placement in soft bone in a non-pretapped osteotomy site.¹²³ Further evolution included an increase in the number and angle of the cutting threads, a conical tip with 3 cutting edges, and a larger bone chip chamber.^{124,125} Other manufacturers have also modified the basic V thread and body shape for simpler, more efficient placement. Still other manufacturers use a reverse buttress thread with a different thread pitch and shallower depth for better load distribution.¹²⁶ Although surgical success rates of more than 95% have generally been achieved in most bone densities, subsequent success following loading appears to be related to bone density.¹²⁷ Reports also indicate that the biomechanical environment has a strong influence on the long-term maintenance of the implant-to-bone interface.^{128,129} The interface can easily be compromised by high stress concentrations that are not dissipated through the body of the implant. Recent attention has been

directed at design features that address variations in occlusal loads and bone densities. Square threads, with a thread angle of 3 degrees, have been proposed to decrease the shear force by a factor of 10 and increase the compressive load, since bone responds more favorably to this type of load distribution.^{36,130} Although theoretical mathematical models project a more functional load distribution surface area, controlled clinical studies will have to validate the biomechanically enhanced implant design. Another recent approach has been the introduction of a rounded thread design that induces "osteocompression" for immediate loading. This is reported to increase surface loading area and provide more uniform stress distribution. Prospective clinical trials are necessary before any definitive conclusions can be drawn. It is appropriate and necessary that biomechanical concepts and principles are now being applied to the design of dental implants to further enhance clinical success.

SELECTION CRITERIA

When osseointegration was first introduced into North America in 1981, the dominant force was the Brånemark implant. Few manufacturers were on the scene, and there was a paucity of selection and training. Approaching a new century, some 19 years later, more than 25 manufacturers compete for market share in the United States alone. Worldwide, the number of implant companies is at least 4 or 5 times greater. Table 1 lists 21 manufacturers who responded, either completely or in part, to a questionnaire related to their products. The industry has gone from 3 or 4 basic designs to more than 95 variations, clones, and proprietary designs. The clinician has more than 1,300 implants and 1,500 abutments to choose from that vary in material, shape, size, diameter, length, surface, and interface geometry. Reported recommended tightening torques range from none given to 1 to 5 per manufacturer. Eleven companies manufacture implants from titanium alloy, 7 from CPT4, 6 from CPT3, and 1 each from CPT2 and CPT1. Two specifically indicated that even though they use CPT3 and/or CPT4, it has the elemental purity of grade CPT1 (Astra Tech and Implant Innovations). Seven elected not to report tolerance specifications, which may mean that they are proprietary secrets, exceptionally good, or embarrassingly poor. Thirteen reported tolerance specification at $\pm 12.7 \mu\text{m}$ or better. In the mid- to late 1980s the industry standard was $\pm 25.4 \mu\text{m}$, which meant that critical areas on the implant could vary by as much as $51 \mu\text{m}$. Based on the survey

results, that standard has been improved to half that much (26 μm). The best tolerance reported was 6 μm (Friadent), with several others close behind at 8, 10, and 16 μm . The number of inspections given to an implant body, from the start of production to inclusion into inventory, ranged from 3 to 41, with the majority reporting between 8 and 20 inspections.

With so many choices, so much advertising, and so little reliable scientific data available, how does one choose? As starters, perhaps ethical conduct, corporate morality, professional conduct, and veracity in advertising and promotion could be considered. From a purely personal clinical perspective, there are 10 criteria: (1) predictable osseointegration; (2) controlled clinical studies that validate performance over a 5-year period or longer in different bone quality, loading, and restorative situations; (3) optimal surface interaction with bone; (4) prosthetic flexibility and applications; (5) cost-effectiveness—quality versus cost; (6) excellent tolerances; (7) tissue friendly/interface seal; (8) interface stability/screw stability; (9) user-friendly, ie, easy surgery, easy restorative; and (10) optimal emergence profile and esthetics. Perhaps engineering elegance, simplicity, refinement, and design logic can also help in the selection process. Presently, no one single design or manufacturer answers to perfection all of the above criteria and considerations because of the variance of the very substrate under consideration. Fortunately for the profession, the clinician, and the patient, today several come very close to meeting those needs.

QUALITY CONTROL AND VALIDATION

The Food and Drug Administration (FDA) regulates all endosseous implants sold in the United States. At one point, implants were placed in the Class III medical devices category, which requires premarket approval. That would have entailed controlled preclinical and clinical studies documenting an implant system's efficacy before it was allowed to enter the marketplace.¹³¹ Since then, implants have been changed to a premarket notification submission (PNS), which is far less rigorous. In general, to gain FDA approval, the manufacturer must specify the intended use (edentulous, partially edentulous, single-tooth); provide a detailed narrative of the design characteristics, including diagrams, material specifications, and tolerances; provide sterilization information and labeling details; submit the results of static and fatigue testing in compression and shear, along with corrosion tests and toxicology tests only when a new material is used that has not been identified in a previously marketed device. Animal

and/or clinical studies are required only for implants with a diameter of less than 3 mm and lengths shorter than 7 mm and for abutments with angulations greater than 30 degrees. Once the manufacturer receives PNS clearance, the Good Manufacturing Practices—Quality Systems Regulations (GMP/QSR) come into play. The GMP/QSR act as an “umbrella” quality control system that covers the design, production, and distribution of all medical devices. The regulations specify general objectives such as “calibration of equipment,” “sterilization monitoring,” etc, rather than specific methods. In most instances, the method is left up to the manufacturers' standard operating procedure, and the FDA conducts quality systems audits to monitor the GMP practices of the company. In essence, little has changed since 1982, and new implants are still introduced in the marketplace on the basis of prior art, not on controlled premarket clinical testing. However, to the credit of the FDA, it has impacted positively specific critical areas of the manufacturing process. For those interested, one can go online to the FDA (www.fda.gov/cdrh), select The Center for Devices and Radiological Health and enter the Medical Devices Quality Systems Manual (Small Entity Compliance Guide) to review the requirements.

Currently, the ADA still has a professional products acceptance program for implants. Although well intended, the ADA criteria for acceptance or partial acceptance are less than rigorous. They do require a modest level of clinical validation. The ADA website lists 7 manufacturers that have acceptance or provisional acceptance (Astra Tech; Bicon; Nobel Biocare; Oratronics, New York, NY; Paragon; ITI-Straumann; and Sulzer Calcitek) for their products. With such modest requirements, it is surprising that all manufacturers do not submit their product for the quasi-endorsement of the organization that theoretically looks after the best interest of the profession and the dental consumer. A natural conclusion would be that such an endorsement is meaningless to many clinicians, who purchase products based on perceived marketing success, rather than scientific and clinical documentation.¹³² Manufacturers are driven by the marketplace. If scientific documentation were critical to their success, they would likely pursue it for economic reasons and not altruistic ones.

Considerable interest has been generated of late in the ISO (International Organization for Standardization) standards. The object of the ISO is to facilitate international unification of standards. ISO9001 and ISO9002 are models for quality assurance in design, development, production, installation, and servicing. The ISO applies generic standards across

all industry types for quality and assurance, but not for company-specific standard operating procedures. ISO9002 differs from ISO9001 in that it applies to companies that only manufacture and do not design or develop products. EN46001 and EN46002 detail the application of ISO9001 and ISO9002 to medical devices and dictate compliance to the Medical Device Directive, which is specific to medical device manufacturing. It is more or less a way to assure that if a company states it uses cp titanium grade 1, sterilizes with radiation, tolerances its implants to $\pm 12.7 \mu\text{m}$, the exact same universal criteria are used to determine the validity of the specific material or process described by that company. In effect, ISO inspects the manufacturer to evaluate whether the manufacturer does exactly what is claimed and whether stated standards are met. The CE mark indicates compliance. This standardization process is definitely a step in the right direction and levels the playing field in a world market economy.

However, many clinicians are still under the illusion that in the area of dental implants, controlled clinical studies in animal and human models and material science evaluations are generally the basis for new product release and development. Reviewing the refereed dental literature results in a much different view. Eckert et al reviewed published articles supplied by selected manufacturers in 1991 and 1995 that were used to validate their implants and concluded that only 1 company survived their scrutiny.¹³³ Although the criteria were quite rigorous and perhaps a bit biased, the point was well made: that there is insufficient scientific documentation available to have confidence in selecting many of the products available. In reviewing the literature, the most prolific documentation is for the Brånemark System, Astra Tech, ITI-Straumann, and Endopore and moderately so for Friadent, Calcitek, and Implant Innovations. Some manufacturers have no published clinical studies or documentation at all. The overriding consideration is not to stifle unique new entries into the arena with additional controls, but at the very least to have adequate documentation that whatever is being touted actually lives up to the claims that are made.

THE FUTURE

The long-term predictability of dental implants is now a well-documented fact. Virtually all the major manufacturers can document success rates greater than 90%, and the more refined systems have achieved well above that number for more than 10 years. A variety of implants work and work well in

the hands of the astute clinician. The problematic area has been the long-term stability of the abutment and the prosthesis. Tremendous progress has been made in this area because of a variety of factors. First and foremost, critical machining tolerances have improved over the past 20 years and will most likely continue to improve with additional advances in technology and intense industry competition. Abutment connections have been re-evaluated from an engineering standpoint and have undergone significant improvement and refinement. Much has been learned in the areas of screw technology, torque requirements, and application. Although considerable redundancies in abutment design exist, subtle differences between the components from the different manufacturers are evident, notable, and frequently important clinically. Entire new interface geometries have been made available that have improved abutment stability and simplified the restorative process. The transition to internal connections has been gradual but profound. During this writing, 2 new internal connections and an internal interface clone have been introduced. Industry-wise, it is very reasonable to conclude that all major manufacturers that currently do not have an internal connection in their design options are working toward that end. An increase in the dimensions of the external hex, along with improved mating and tolerancing, modified load platforms, better screws, and higher torque application, have extended the life of the design. However, with the excellent variety of new interfaces available, it is unlikely that the external hex will survive very long into the new millennium. The internal connections that are available today are more stable, physically stronger, easier to restore, more amenable to excellent esthetics, and definitely more user-friendly. The new entries in this arena have learned a great deal from the hexagonal experience and have applied it to all aspects of implant treatment.

The concerted effort by many manufacturers to improve the quality and fit of their products has also resulted in renewed security and confidence for patients and clinicians alike. Development of more stable and secure implant/abutment interfaces has transitioned the profession away from the cumbersome and problematic screw-retained FPD and single-tooth restorations to the more user-friendly cementable prostheses. This trend will continue, and it is predictable that screw-retained FPD and single-implant restorations will meet the fate of the gold foil restoration. This trend will inevitably continue, as the result of market pressure for simplicity and stability.

Increased demands for esthetic solutions will continue. Additional refinements in ceramic technology will lead to further improvements in all-ceramic and

ceramic/metal combination abutments. Specific implant/abutment interface designs (Friadent, Replace Select, Camlog, Astra Tech, and others) are well poised to use this technology because of an internal connection that permits potentially greater porcelain thickness at the critical interface area.

It is nearly impossible to keep up with the enormous array of hardware available in this competitive developing technology. One small but very commendable inroad to user friendliness has been the color-coding of components available in some systems. It is strongly urged that color-coding of not only the components but the packaging be universally employed throughout the industry. In concert with simplicity, some of the manufacturers have made tremendous strides in catalog simplification. Excellent examples are Friadent, Nobel Biocare, Steri-Oss, Implant Innovations, and Astra Tech.

The dental implant and its related components have come full circle. The original 3.75-mm Brånemark implant diameter was the fortuitous result of the presence of 4-mm titanium bar stock in Göteborg, and its hexagonal interface design was a simple means to place the screw in bone. Today, for the most part, considerable engineering sophistication and internal evaluation goes into new component design. Every detail is planned for optimal performance and marketing distinction. Great progress has been made and will continue to be made well into the next century. In some respects, however, some things never change. The absence of independent laboratory evaluation and controlled clinical trials before the release of new products to the profession is still prevalent. New designs should be developed using scientific methods rather than speculation, professional opinion, and marketing posture.¹³⁴ Perhaps that will no longer be an issue in the next millennium, as the profession matures and evidence-based treatment demands scientific documentation before utilization.

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