

**Implants and Components: Entering the New Millennium.  
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## **Introduction**

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

One of the essential tenets to obtain osseointegration was the atraumatic insertion of a titanium screw into viable bone and a prolonged undisturbed, submerged healing period. By definition, this required a two stage surgical procedure. To comply, a coupling mechanism for implant insertion and the eventual attachment of a transmucosal extension for restoration was explored. The initial coronal design selected for 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 we approach twenty years of osseointegration in clinical practice in North America much has changed. The efficacy and predictability of osseointegrated implants is no longer an issue.<sup>1-7</sup> 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.<sup>8-10</sup>

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.<sup>11-13</sup>

The external hexagonal design, *ad modum* Branemark, originally intended as a coupling and rotational torque transfer mechanism, consequently evolved by necessity, into a prosthetic indexing and antirotational mechanism.<sup>14, 15</sup> The expanded utilization of the hexagonal resulted in a number of significant clinical complications.<sup>8-11, 16-22</sup>

To mitigate these problems the external hexagonal, its transmucosal connections and their retaining screws has undergone a number of modifications.<sup>23</sup> In 1992, English published an overview of the then available external hexagonal implants, numbering 25 different implants, all having the standard Branemark hex configuration.<sup>14</sup> 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, 2.4, 2.7, 3.0, 3.3, and 3.4 mm depending on the implant platform. The available number on 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 and thread design and torque application.<sup>23,24</sup> Entirely new second and third generation interface coupling geometries have also been introduced into the implant milieu to overcome intrinsic hexagonal deficiencies.<sup>25-29</sup> Concurrent with the evolution of the coupling geometry were the introduction of a variety of new implant body shapes, diameters, thread patterns and surface topography.<sup>27,28, 30-37</sup>

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, a “narrow“, “standard” and “wide” diameter implant body, a machined, textured, HA and TPS surfaced implant, 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.

### **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 is based on the implant / abutment interface, the body shape, and the implant to bone surface.

### **Abutment / Implant 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 two groups is the presence or absence of a geometric feature that extends above the coronal surface of the implant (Fig.2-4). 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, that consists of two 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.2-4,6-11.

### **Body Geometry:**

The body geometry of the endosteal implant is characteristically cylindrical in shape. Initially three basic shapes were available, consisting of a threaded screw (ad modum Branemark), a press fit cylinder (ad modum IMZ) and a hollow basket cylinder (ad modum ITI) (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 twenty 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 and ovoid tapered and expanding (Fig.13). Thread patterns have also been modified and range from micro threads near the neck of the implant (Astra), broad macro threads on the mid body (Biohorizons, SteriOss), a variety of altered pitch threads to induce self tapping and bone compression (Implant Innovations, Nobel Biocare), and small limited length threads for initial stability (Basic). Press fit cylinders can be characterized as straight walled, tapered, conical, trapezoidal, and trapezoidal step (Fig14). Additional distinction 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 that can vary in width and angle and the presence of a flared or straight neck (Fig.15). Representative geometries are presented in Fig.13,14.

#### **Implant Surface and Coatings:**

The implant to bone surface has also undergone a number of different developments. The original offerings consisted of machined titanium [Branemark], titanium plasma sprayed (TPS) [ITI group] and hydroxylapatite coated (HA) [Calcitek-Sulzer] implants. Progressively, the implant surface has been altered, and sintered and coated with spherical titanium powder, treated with leaching agents ( $\text{NO}_3$ , HF, HCl,  $\text{H}_2\text{SO}_4$ ), air abrasives / particulate blasting ( $\text{Al}_2\text{O}_3$ ,  $\text{Ca}_3\text{SO}_4$ ,  $\text{TiO}_2$  of different sizes [25 to 250  $\mu\text{m}$ ]), singularly or in combination in order to obtain a controlled surface texture to increase cellular activity and bone to implant contact (BIC).<sup>38-41</sup> Little question remains that a controlled surface texture enhances cell activity, increases BIC and the strength of integration.<sup>42-47</sup> 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), TiOblast (Astra), SLA (ITI), Osseotite (3i), Osteo (OIC), RBM (Lifecore) MTX (Calcitek), THD (SteriOss) and others.<sup>44,48-50</sup> 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.<sup>26</sup> The results of ITI research on surface characteristics has changed its focus from all TPS coated implants, to the sandblasted acid etched surface (SLA) that produces significantly greater BIC (55%) in comparison to TPS (37.5%).<sup>43</sup> HA coatings are also applied to the implant bodies with plasma spray technology.<sup>51</sup> Highly bioactive and osseoconductive, HA coated implants demonstrated earlier and

greater bone bonding.<sup>38,43, 52,53</sup> Although there are proprietary differences relative to crystallinity and amorphous content, the surface coating has generally remained the same with one notable exception. HA coating 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%.<sup>54,55</sup> Other commercial coatings range in crystalline HA content from 45% to 73%. The MP-1 coating exhibits significant decreased solubility over a wide range of pH.<sup>54</sup>

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.<sup>56-61</sup>

An interesting recent innovation in surface technology is the combination of two 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).

### **The Abutment Connection:**

Definitive abutment connections can be characterized in many different ways. The basic categories available are: 1) one and two piece flat top abutments, 2) one and two piece conical shouldered, 3) UCLA type plastic castable, 4) UCLA machined / plastic cast to cylinders, 4) UCLA gold sleeve castable, 5) one piece fixed post, 6) two piece fixed shoulder, 7) pre- angled fixed, 8) telescopic millable post, 9) ceramic, 10) single

tooth direct connection and 11) one and two piece overdenture abutments (Fig. 16,17). The initial connections were various length sleeves that mated to the implant with connecting screws (abutment screws) or one 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 marine 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 fully edentulous to FPD applications resulted in the development of two piece conical abutments that brought the coronal area ever closer to the implant interface and permitted angulation changes.<sup>62</sup> The advent of the UCLA connection eliminated the intermediate transmucosal connection completely and improved esthetics dramatically (Fig. 16).<sup>63, 64</sup> The concept was modified to include, an all machined metal cast to cylinder, a machined interface with a plastic burn out 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, CeraOne® (Nobel Biocare) and STA® (3i) , that would receive single unit cemented restorations (Fig.16).<sup>65-67</sup> 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), that permit replication of natural tooth cervical profiles, and be use in esthetic areas with limited soft tissue height with virtually no facial metal collar (Fig.16).

In a similar vein, machined one and two piece straight and pre-angled cement to abutments became readily available. The driving force was 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 two piece cement to straight and angled abutment that permits axial correction and shoulder modification to conform within a given clinical situation. Refined examples of this design type are the Angled Esthetic Abutment® (SteriOss) and MH-6 (Friadent) Fig.17).

Additional demand for optimal single implant esthetics has led to perhaps the most exciting development in implant abutment design, the ceramic abutment. <sup>68-71</sup> 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.<sup>72</sup> The same is true for the contact of aluminum oxide with the implant titanium 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.<sup>73</sup> The CeraOne® abutment (Nobel Biocare) mentioned previously, has prefabricated aluminous 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 ceramo-metal 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.<sup>71</sup> 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, two piece machined cast to or plastic sleeves for direct connection to the implant, one or two piece conical abutments and one or two 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 keepers and low profile Zaag® type of attachments. Representative abutment connections are illustrated in Fig.16,17.

### **A critical look at the abutment / implant interface:**

Currently there are some 20 different abutment / implant interface geometric variations available. The geometry is important because it is one of the primary determinants of joint strength, joint stability, 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 involves the external hexagonal. This is primarily due to its extensive use, the broad number of prescribed clinical applications, and 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 fully edentulous arch. All the implants were joined together with a rigid metal superstructure structure and the external hexagonal and simple butt and bevel joints performed quite well.<sup>1,2</sup> Long term stability simply required an accurate 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 is exposed to more rigorous load applications.<sup>74,74</sup> The retaining screw is no longer shielded from stress and is subject to lateral bending loads, tipping and elongation that result in joint opening and screw loosening.<sup>76-79</sup> Short, narrow external geometry is particularly vulnerable due to the limited engagement of its external member and the presence of a short fulcrum point ( small platform), when tipping forces are applied.<sup>80, 81</sup> This deficiency was originally noted by Branemark, who recommended that the

external hex connection should be a minimum of 1.2 mm in height to provide both lateral and rotational stability, particularly in single tooth applications.<sup>82</sup> 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 that ranging from 6 % to 48%.<sup>8-11, 16-22, 83,84</sup> Consequences of maintaining an unstable geometry in practice can be significant. A 22 month follow-up on external hex implant prosthesis in a private prosthodontic practice reported experiencing loose screws in fixed IP and removable IP at 27% and 32% respectively.<sup>85</sup> The necessary adjustment and repairs were generally done at the prosthodontists expense, with a mean office adjustment cost per visit of \$106. Only 16% were billable to the patient.

During the past ten years all the 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 eliminate the joint problem entirely. Haas et al reported on 76 single hex I/A interfaces with the high torque and improved screw configuration and observed 16% loose screws during a mean observation time of 22.8.<sup>86</sup> In a follow up 5 year report, the same authors report a 9% abutment screw loosening occurrence during the last three years. Subsequent modification of hex height and width in concert with an increased loading platform, have further improved performance in laboratory tests<sup>87,88</sup> Several factors however, still remain unresolved. Clinically, it is often difficult, for even 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 however, 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 prosthesis framework.<sup>89</sup> Minute rotational changes at a single abutment location can result in misfit of the superstructure. This problem is compounded further in complex, multiple implants 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.<sup>90</sup> The wider and taller hexes configurations have reduced this problem since they are easier to machine and generally have tighter tolerances.<sup>87</sup> As such they have demonstrate reduced rotational misfit, but have not completely eliminated it. Two different design changes however 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 closely tolerance hexagonal abutment recess that is friction fitted onto the hex (Swede-Vent® TL).<sup>91</sup> The other involves the addition of microstops in the corners of the abutment hexagonal that engage the corners of the implant hex (ZR Abutment®).<sup>92</sup>

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, spline, internal spline and resilient connection.

Of these, the internal octagonal connection (Omniloc®) and the resilient connection (IMZ) are no longer available. The octagonal design, due to its thin walls, 0.6mm 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 Delrin® 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.<sup>93,94</sup> Ownership transfers and distribution right conflicts effectively termination North American sales.

Essentially two 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 one piece narrow diameter (3.3 and 3.5 mm) implant (ITI Narrow Neck®) designed for lower anterior use. The tall, well toleranced octagonal extension allows for 45° rotation, very good lateral and rotational resistance and good strength. The Spline® implant connection consists of six external parallel keys (splines) alternating with six grooves. The abutment has a mirror image design pattern that is engineered to fail before damaging the implant. Spline geometry comes in two designs and three platforms. The 4 and 5 mm platforms have the same geometry and are strong, mechanically stable, demonstrate minimal rotational movement and screw loosening.<sup>29</sup> The spline geometry on the narrow 3.25 implant however, is quite different. Thinner, smaller splines, plus a narrow loading platform results 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 (ITI-Straumann) (Fig.11).<sup>35</sup> 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 one stage surgical protocol.<sup>95-97</sup> Although the connection is called a "Morse" taper, the mating angle between component parts is 8°. A true Morse taper exists at 2° and 4° and has unique self locking characteristics without threads. It is doubtful that the 8° connection without its retaining screw component would remain intact. However, combining the two stabilizing elements has resulted in a strong, stable and predictable connection.<sup>35</sup> Conical connections require precise machining and tolerances for this manufacturer are consistent and excellent. Essentially two 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 antirotation feature and depends entirely on the application of proper tightening torque and, most critical, 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 multi center report on 174 implants reports 8.7% prosthetic and 3.7% cone abutment screws loose at 6 months.<sup>98</sup> An other study,

with a mean observation time of 3.5 years, reported loose screws at 9.1%, screw fractures and abutment complications at 1.5% respectively.<sup>94</sup>

A similar cone screw connection with an 11° taper is available Astra (AstraTech) (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° and 45° conical head. The original 11° 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 prosthesis.<sup>99</sup> In a subsequent report on 517 implants with a five year follow-up, Arvidson et al reports no prosthetic or abutment screw loosening, fracture or complications.<sup>100</sup> Karlsson et al reports a 2 year follow up on 133 implants in the maxilla and Mandible with FIP and RIP with complications at one and two years of bridge screws loose: 4%, 3%, loose abutments: 2.3%, 0.75% respectively and abutment fractures of 1.5% during the first year only.<sup>101</sup> This geometry has been modified to a two piece abutment with an antirotational hex feature at the end of the cone (ST) 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 supports good stability.<sup>102</sup> With respect to strength characteristics between conical and an external hex butt joint, the conical joint is approximately 60% stronger.<sup>102</sup> Conflicting evidence exists with respect to the cone screw requiring a higher loosening torque than was originally applied. Sutter et al has reported that the loosening torque required for ITI connections was greater (124%) than the original tightening (input) torque.<sup>35</sup> Other studies have

shown that for both the 8° and 11 degree connection, the loosening torque is 80% to 85% of the original tightening torque.<sup>103,104</sup>

Several internal hexagonal configurations are available (Fig.6,7,9,10). 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° taper that provided an interference friction fit ( ScrewVent TL®) (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.<sup>105</sup> The authors note that “stress analysis...revealed that maximum compressive stresses are concentrated within the cylindrical collar and upper 1/5 of the implant body. This stress is transferred to...bone.. this may be explanation for ... ongoing bone loss...”.<sup>105,106</sup> In the 4.5 and 5.7 mm bodies, a horizontal shelf has been added immediately below the lead in bevel. That, 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®) (Fig.7). The hexagonal is interposed between a superior and inferior cylinders on the abutment connection. The hex provides rotational resistance and 60° indexing. The cylinders provide excellent lateral load resistance,

resistance to joint opening, protection of the abutment screw and very high strength values.<sup>107</sup> When the joint does fail, it is the abutment that 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®).<sup>108</sup> Mechanical tests indicate good strength, minimal rotation, superior screw stability and resistance to loosening, along with excellent machining tolerances.<sup>109,110</sup> A wide variety of abutments are available and they are exceptionally easy to seat. Currently available in 3.8, 4.5, 5.5 and 6.5 mm platforms, the manufacturer is due to release a narrow platform ( 3.3 or 3.5) in 2000.

Two new internal designs, similar in concept, yet quite different have entered the market. Replace Select® (Nobel Biocare/SteriOss) 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, convenient seating and indexing. The second entry, Camlog® (Altatec Biotechnologies) 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.<sup>111</sup> Three lateral cam projections provide indexing and antirotation. The Camlog® implant body is a cylinder hybrid with six widely spaced threads at the superior one third of its body. Currently, no data is available from the manufacturer or in the literature on either design.

A true Morse tapered implant interface connection is available (Bicon) without any threaded component (Fig.10). The abutment has a 1° - 2° tapered post that fits into a

smooth mirror image shaft within the implant. The abutment is seated with a sharp blow on the long axis of the implant. It requires a dry clean abutment post and implant shaft in order 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 intra orally 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, where the screw takes little or no load, provides intimate contact with the implant walls to resist micro movement and results in a strong stable interface. The classic article by Mollersten et al clearly indicated the strength advantage of an internal connection.<sup>107</sup>

In order 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 is 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 prostheses fit, and occlusal load control are equally important.

#### **Abutment Screw design:**

In a further effort to overcome joint instability problems, the abutment screw has evolved to maximize preload and minimize loss of input torque to friction.<sup>23</sup> It currently consist of a pan (flat) head seat, long stem length, and six thread lengths (Fig.18). The increased stem length aids in attaining optimal elongation and shorter thread lengths reduce friction.<sup>112</sup> When less input torque is lost to friction and heat, a higher preload is achieved.<sup>113</sup> The single most significant factor that determines the bolting characteristics of the screw is the material it is made of 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, due in part to “galling,” a form of adhesive wear that occurs during the intimate sliding contact of two like materials limits the preload characteristics of titanium screws.<sup>114</sup> Hence the transition to the gold-alloy screw.<sup>67</sup> Gold-alloy screws have a lower coefficient of friction, can be tightened more effectively to higher preloads, and won’t 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.<sup>115</sup> Current gold screw metallurgy varies between manufacturers, ranging in gold content from 64.1% to 2% gold with yield strengths of 1270 N to 1380 N.<sup>116</sup> Proper handling of gold screws is a concern as the screw threads are meant to deform upon tightening. It is therefore recommended that the gold screw use is limited to the final clinical insertion 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 / SteriOss) 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%.<sup>115</sup> The reported

data indicates 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  $\mu$ m of pure gold. With a tightening torque of 32 Ncm, the manufacturer reports a 24% increased preload for the coated screw.<sup>117</sup>

Available data on the effectiveness of friction-reducing coatings is primarily manufacturer-based. Although theoretical calculations predict increase attainable preload, numerous tests on the preload of lubricated and unlubricated screws indicate that there may be no significant statistical difference.<sup>118,119</sup> Another concern relates to the wear of the coated/plated screws after repeated tightening sequences. The effectiveness of this technology on screw joint stability still has 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.<sup>120,121</sup> For threaded screws, it was intended as a rescue implant, when the osteotomy site was oversized.<sup>31</sup> Since then, it has demonstrated numerous clinical advantages.<sup>122,123</sup> It is especially appropriate in posterior areas requiring greater stability and resistance to masticatory loads.<sup>122, 124, 125</sup> The typical design is a straight or tapered screw, a trapezoidal cylinder, a step cylinder or hybrid cylindrical tapered screw.

The most frequently used threaded implants still range in diameter from 3 to 4 mm.<sup>126</sup> The typical 3.75 mm threaded screw implant has a .4 mm wall thickness. With crestal bone loss, it is vulnerable to fatigue fracture. Fracture rates for CP1 3.75mm implants have been reported at 7%, 13% and 16% over respective periods of 5, 10 and 15

years.<sup>2</sup> In contrast, 5mm and 6 mm implants are 3 and 6 times stronger and the risk of fracture is eliminated.<sup>127</sup> Irrespective of physical properties, a wider body significantly increases the available surface for integration and lowers stress to the bone implant interface.<sup>122</sup> 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.<sup>122,124</sup> This reduces the potential for crestal overload that is typically associated with bone loss. A WP also increases abutment stability by reducing the occlusal table to loading platform cantilever and the concomitant stress to the abutment screw.<sup>122,124</sup> Regardless of the size of external hex engagement, WP implants perform exceptionally well in cyclic loading tests and demonstrate increased resistance to screw loosening.<sup>128</sup> The wider loading platform also permits an emergence profile that correlates more closely to the natural tooth it replaces.<sup>123</sup> Early clinical experience with WD threaded implants was guarded as anecdotal reports of increased bone loss surfaced. Although limited data appears in the literature, evolutionary changes in thread patterns, collar design and a gentler and more fastidious surgical techniques have been recommended to overcome these initial difficulties.

With the advent of single tooth replacement also came the need for narrow diameter and platformed implants for maxillary lateral and mandibular incisors. The smallest diameter external engagement implants available are 3.25 mm (hex) and 3.3 mm (octagon). Due to 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 due to inherent wall thickness limitations and

fracture potential. The narrowest internal engagement implant currently available is the 3.5 mm Astra implant. In two prospective studies, one with a 2 year and the other with a 5 year follow up, the implant success rates were 97.7% and 98.7% respectively with minimal prosthetic complications.<sup>129, 130</sup> Interface bending strength of the small diameter cone screw connection was 40% greater than the a 3.75mm hex top indicating that this diameter and interface can be used with confidence.<sup>102</sup> Little published data is available on any other “narrow” diameter connections.

### **Thread design.**

The original Branemark screw introduced in 1965 had a V shaped thread pattern as a means of insertion into a threaded osteotomy.<sup>1,2</sup> The design was modified in 1983 as a self tapping fixture for insertion in soft bone in a non pretapped osteotomy site.<sup>131</sup>

Further evolution included an increase in the number and angle of the cutting threads, a conical tip with three cutting edges, and a larger bone chip chamber.<sup>132,133</sup> Other manufacturers have also modified the basic V thread and body shape for simpler, more efficient insertion. Still other manufacturers use a reverse buttress thread with a different thread pitch and a shallower depth for better load distribution.<sup>134</sup> 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.<sup>135</sup> Reports also indicate, that the biomechanical environment has a strong influence on the long term maintenance of the implant to bone interface.<sup>136,137</sup> 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  $3^{\circ}$ , have been proposed to decrease the shear force by a factor of ten and increase the compressive load, since bone responds more favorably to this type of load distribution.<sup>37,138</sup> 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. 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**

In 1981, when osseointegration was first introduced into North America the dominant force was the Branemark implant. Few manufacturers were on the scene and selection and training was scarce. As we embark on a new century, some 19 years later, more than twenty five manufacturers compete for market share in the United States. World wide the number of implant companies is at least 4 or 5 times greater. Table 1 lists 21 manufactures who responded, 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 1300 implants and 1500 abutments to chose from that vary in material, shape, size, diameter, length, surface and interface geometry. Reported recommended tightening torque range from none given, to 1 to 5 per manufacturer. Eleven manufacture implants from titanium alloy, seven from CPT4, six from CPT 3 and one each from CPT2 and CPT 1. Two specifically indicated that eventhough they use CPT 3 and/or CPT 4, it has the

elemental purity of grade CPT 1( Astra & 3i). Seven elected not to report tolerance specifications which may mean that they are a proprietary secret, exceptionally good or embarrassingly poor. Thirteen reported tolerance specification at or better than  $\pm .0005$ ". In the mid to late 1980's the industry standard was  $\pm .001$ " ( $\pm 25.4$  microns), which meant that critical areas on the implant can vary by as much as 51 microns. Based on the survey results, that standard has been improved to half that much ( 26 um). The best tolerance reported was 6 microns (Friadent) with several others at 8, 10, and 16 microns. 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 and so much (advertising) and so little information (scientific data) available how do you choose? As starters, perhaps ethical conduct, corporate morality, professional conduct, 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 plus period in different bone quality, loading and restorative situations, 3) Optimal surface interaction with bone, 4) Prosthetic flexibility and applications, 5) Cost effective - quality vs. cost, 6) Excellent tolerances, 7) Tissue friendly / interface seal, 8) Interface stability/ screw stability, 9) User friendly - easy surgery - easy restorative, 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 we are dealing with.

Fortunately for the profession, the clinician and the patient, several do come very close to meeting those needs.

### **Quality control and validation?:**

The FDA regulates all endosseous implants sold in the US. At one point implants were placed in the Class III medical devices category that requires premarket approval. That would have entailed controlled preclinical and clinical studies documenting efficacy before entering the market place.<sup>139</sup> Since then, the PMA have been changed to a PNS (premarket notification submission) that is far less rigorous. In general, to gain FDA approval, the manufacturer has to 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, labeling details, submit the results of static and fatigue testing in compression and shear, and 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°. Once the manufacturer receives PNS clearance, the GMP (Good Manufacturing Practices - Quality Systems Regulations) come into play. GMP / QSR are an “umbrella” quality control system that covers the design, production and distribution of all medical devices. The regulations specifies general objectives such as “calibration of equipment”, “sterilization monitoring”, rather than specific methods. The method in most cases is left up to the manufacturers standard operating procedure (SOP) and the FDA has Quality Systems Audits (QSAs) that monitor the GMP practices of the company.

In essence, little has changed since 1982 and new implants are still introduced in the market place on the basis of prior art and not controlled premarket clinical testing. To the credit of the FDA, it has however impacted positively specific critical areas of the manufacturing process. For those interested, you can go on line to the FDA ([www.fda.gov/cdrh](http://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 is less than rigorous. It does however, require a modest level of clinical validation. The ADA web site lists 7 manufacturers that have acceptance or provisional acceptance ( Astra Tech, Bicon, Nobel Biocare, Oratronics, Paragon, Straumann ITI, and Sulzer Calcitek) for their products. With such modest requirements, it is surprising that all manufacturers don't 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 product based on perceived marketing success rather than scientific and clinical documentation.<sup>140</sup> Manufacturers are driven by the market place. If scientific documentation was critical to their success, they would pursue it for economic reasons and not altruistic ones.

Considerable interest has of late been generated in the ISO standards. ISO is The International Organization for Standardization, the object of which is to facilitate international unification of standards. ISO9001 and ISO9002 are models for quality

assurance in design, development, production, installation and servicing. ISO applies generic standards across all industry types for quality and assurance BUT NOT for company specific SOP's (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 dictates compliance to MDD (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 +/- .0005", the exact same universal criteria are used to determine the validity of the specific material or process describe by that company. In effect, ISO inspects the manufacturer to evaluate if the manufacturer does exactly what he said he does and if the stated standards are met. The CE mark indicate compliance. This standardization process is definitely a step in the right direction and levels the playing field in a world market economy.

Many clinicians are however 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 one company survived their scrutiny. <sup>141</sup> 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 Branemark System, Astra Tech, ITI Straumann, Endopore and moderately so for Friadent, Calcitek, and 3I. Some manufactures 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 to at the very least, 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 of the major manufacturers can document success rates greater than 90% and the more refined systems well above that number for more than ten 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 due to a variety of factors. First and foremost, critical machining tolerances have improved over the past twenty years and will most likely continue to improve with additional advance 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 area of screw technology, torque requirements and application. Although considerable redundancy in abutment design exists, subtle differences between the components from the different manufacturers is 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 the writing

of this paper, two new internal connections and an internal interface clone have been introduced. Industry wise, it is very reasonable to conclude that all the majors that currently don't have an internal connection are working towards that end. Increasing 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 much 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 are 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 of the manufacturers to improve the quality and fit of their products has also resulted in renewed security and confidence for the patient and the clinicians alike. Development of more stable and secure abutment /implant interfaces has transitioned the profession away from the cumbersome and problematic screw retained FPD and single tooth restorations to the more user friendly cementable prosthesis. 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 due to 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 and others) are well poised to use this technology due

to 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, SteriOss, Implant Innovations and Astra.

The dental implant and its related components has come full circle. The original 3.75 mm Branemark implant diameter was the fortuitous result of the presence of 4 mm titanium bar stock in Goteborge, and its hexagonal interface design, a simple means to insert the screw in bone. Today, for the most part, considerable engineering sophistication and internal evaluation goes into new component designs. 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 trails before the release of new product to the profession is still with us. New designs should be developed using scientific methods rather than speculation, professional opinion and marketing posture.<sup>142</sup> Perhaps that will no longer be an issue in the next millennium, as the profession matures and demands scientific documentation before utilization.

**Reference:**

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