

SDS Dental Implants Clinical Trial

A Preliminary Prospective Trial of 100 SDS Dental Implants And Their Ability to Reduce the Incidence of Crestal Bone Loss:

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Introduction:

The physiologic response of the osseous substrate surrounding the osseointegrated implant can be separated into three general categories. The first phases of primary site preparation and the steps associated with osseointegration, using cylindrical endosseous implants, have been well documented in the literature¹. Bone loss associated with this first phase has been attributed to poor surgical technique, inadequate quality and quantity of bone, or preexisting osseous defect not previously controlled². The second phase would be described as uncovering phase. Bone loss associated with this surgical phase is scarcely reported in the literature due to the noninvasive nature of the procedure.

The third phase is that of prosthetic loading and function. Bone loss in this phase is multi-factorial and well reported in the literature³. These “ailing and failing” implants have introduced a new discipline, within the field of implant dentistry, attempting to reverse or repair the obvious clinical problem of crestal bone loss⁴. Reports of excessive crestal bone loss have been suggested to be a result of plaque-induced Peri-implantitis⁵ or occlusal overload that can produce excessive stresses in the crestal bone surrounding the implant.⁶ Publications demonstrating bone loss at the crestal ridge of implants associated with microbial infections occurred only after occlusal overload⁷. Isidor’s monkey study demonstrates that occlusal overload is more responsible for crestal bone loss than plaque accumulation with a greater than three fold difference⁸. Due to the nature of the connection of an osseointegrated dental implant and the surrounding bone, both photoelastic and finite element analysis demonstrate the highest concentration of stress at implant/bone interface, specifically within the area of crestal bone⁹. High crestal implant/bone stresses may also accelerate the accumulation of plaque in a similar way as occlusal stress increases

¹ 11.2

² 9.1,2,3,4

³ 10.6 4.3,5,6

⁴ 4.1,2

⁵ 7.2

⁶ 7.3

⁷ 10.6

⁸ 7.6

⁹ 7.7

plaque accumulation around natural dentition¹⁰. In addition forces placed upon dental implants exceed that of natural dentition. Studies report the threshold of tactile perception to be up to 50 times greater in patients with dental implants as opposed to natural dentition. This subjects the dental implant to increased risk of occlusal overload¹¹. The desmodontal structures refer to all physical, chemical and physiological structures associated with the myriad of events within the dental and periodontal attachment apparatus. This system is a complex sympathetic and parasympathetic coordination of all neuro-muscular structures of the myofacial system designed to prevent overload and harmful assaults to the natural dentition¹². This is missing in peri-implant region because of the missing desmodontal structures¹³. Implants are in greater risk do to the stresses causing crestal bone loss, than natural teeth due as a result of the absence of the desmodontal structures¹⁴. Late failure of osseointegrated dental implants is most commonly the result of bone loss at the crest of the alveolar ridge¹⁵. The clinical reality of this ever-present problem in implant dentistry has led to a myriad of solutions.

In recent years studies focused on improving the clinical success of osseointegrated implants by evaluating the effect of design and shape of the fixtures¹⁶. Bioengineering has played a major role with increasing effectiveness in determining the optimum design in both the implant prosthesis and implant design¹⁷. When geometry of a dental implant has been analyzed, thread configuration has been shown to be the most favorable design for ideal stress distribution¹⁸. However it has yet to be scientifically and clinically proven which thread configuration would be most favorable in evenly distributing the stress of occlusion.

Method and Materials:

The objective of this prospective study is to clinically analyze the effectiveness of the SDS dental implant (manufactured by ACE Surgical Photo 1) in minimizing crestal bone loss. The SDS implant (Photo 1) is made of type IV commercially pure titanium. The prosthetic connection is the industry standard external hex (Photo 1 A). The transition from the prosthetic connection to the patented thread configuration is characterized by a highly polished titanium surface (Photo 1B). The coronal or proximal 6.5mm of the thread (Photo 1C) is the patented stress diversion thread (SDS) configuration. This unique design varies in surface area, angle of incidence, and distance from the moment load. One continuous thread, that progressively changes the thread angle and inner minor diameter while holding the major diameter at 3.75mm. This thread is mathematically designed to divert the stress of occlusal load away from the crest of the ridge and divert these harmful stresses to the centroid

¹⁰ 7.8

¹¹ 7.9

¹² 8.1

¹³ 8.2

¹⁴ 8.3

¹⁵ 7.1

¹⁶ 6.8

¹⁷ 6.9

¹⁸ 7.17

of the body. By geometrically drawing the stress closer to the body (Photo 1 E), this design more evenly introduces favorable stresses to encourage bone maturation. The thread transitions into a continuous self-taping tapered design for user-friendly insertion. The 'cut out' in the driving thread (Photo 1 E) serves to drive autogenous bone fragments into the voids of the SDS thread configuration (Photo 1 C).

Photo 1

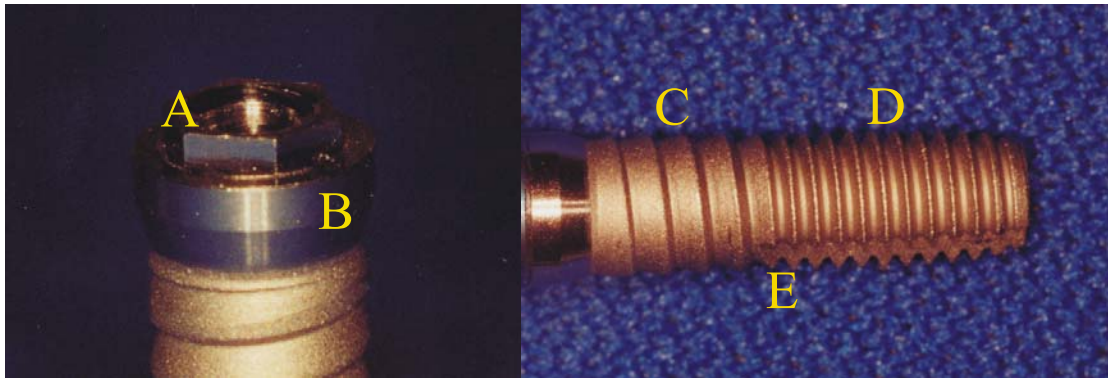


Figure 1

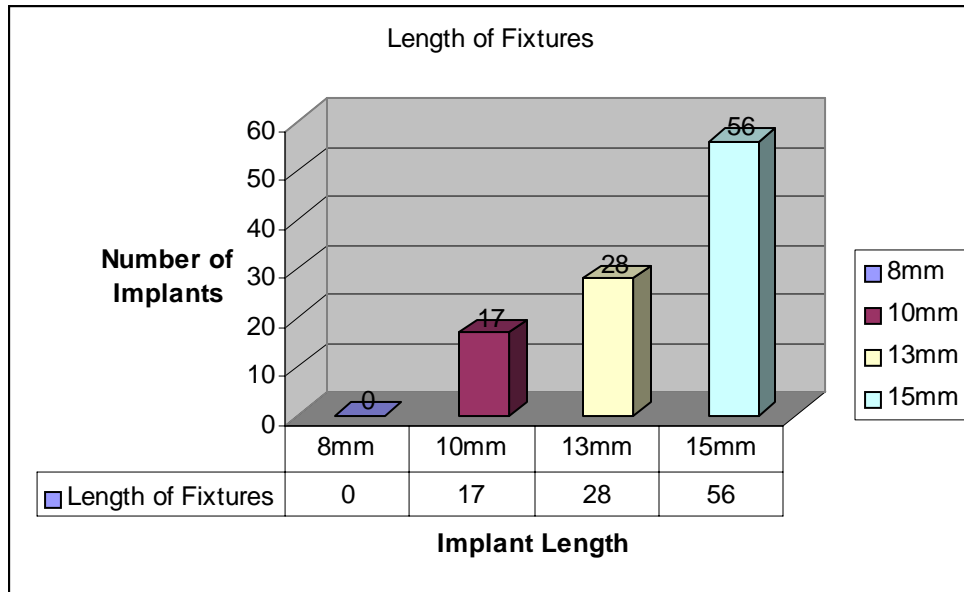


Figure 2

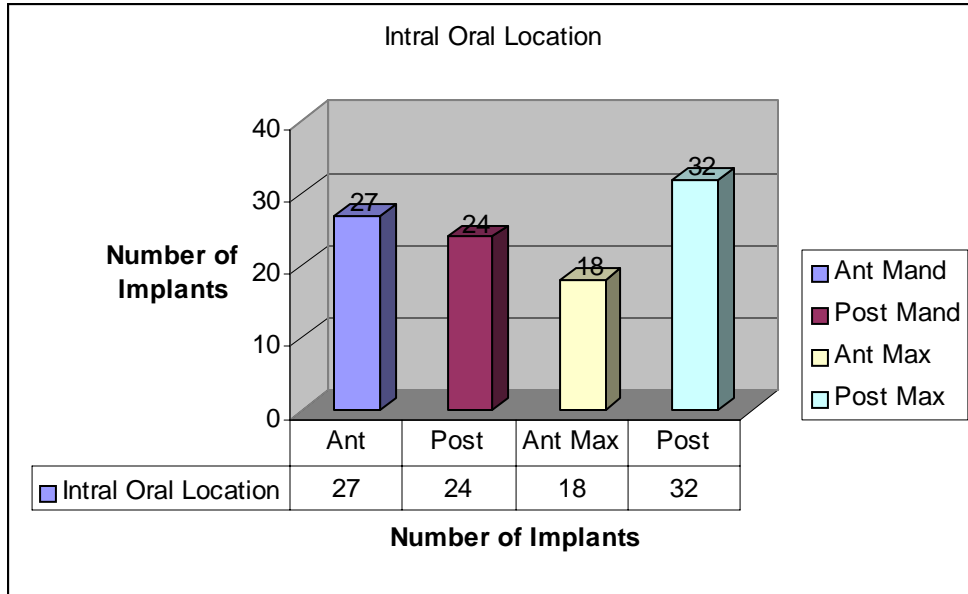


Figure 3

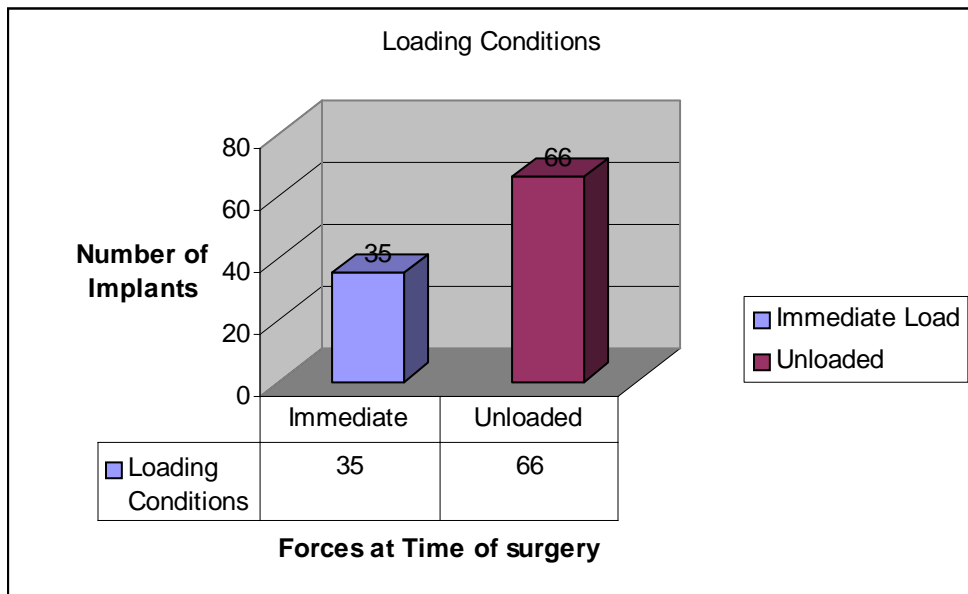
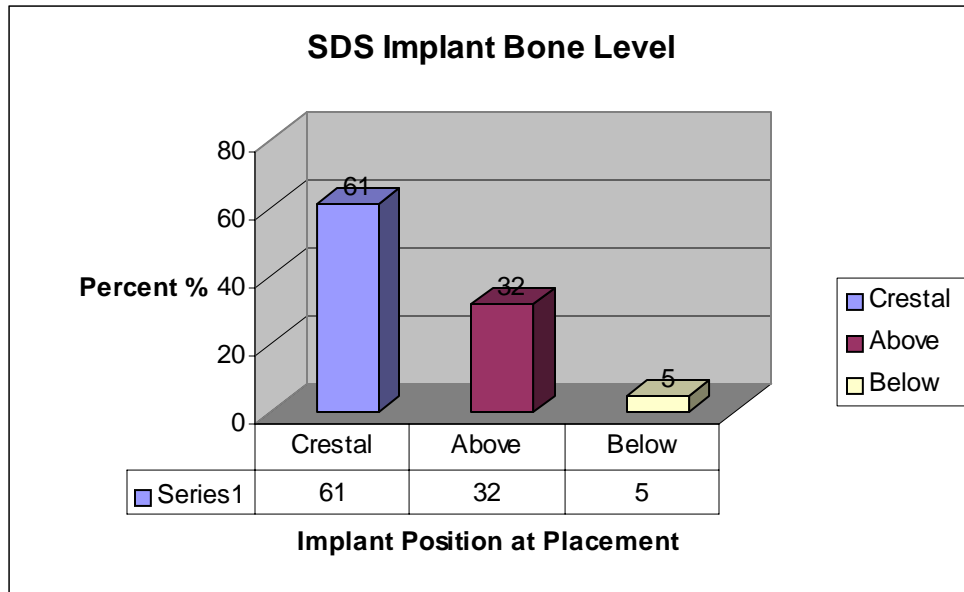


Figure 4



One hundred SDS dental implants have been placed in a variety of clinical applications. Figure 1 is a graft demonstrating the number and length of the SDS implant used in the study. Each implant in the study is documented both radiographically and visually in terms of specific patient, graft material used, loading conditions, and position of the implant relative to the crest of the ridge. (Figures 2,3 & 4) Digital radiographs will be used in the study to evaluate the qualitative and quantitative changes in the surrounding bone. The computer image processing programs can be used efficiently to capture identify and analyze the radiographic density of the bone and other structures in the x-ray field as small as 0.04mm in length¹⁹.

Figure 5 is an example of an SDS implant immediately placed in the extraction site of position of tooth number nine. The Implant was placed using a closed procedure and augmenting the residual defect using similar protocol reported in the literature of PRP and select graft material²⁰. Note figure 5 digital x-ray 1.B that is the four-month post surgical radiograph. Zone 1 clearly outlines the newly formed bone at the implant/prosthetic connection. The comparative analysis of the osseous response will be evaluated based on similar protocols already reported in the literature²¹. Within a given digital radiograph, using constants (the Implant body), the relative changes to the surrounding tissues can be accurately compared and analyzed. As the grid area is altered, by remodeling of the surrounding tissue, the

¹⁹ 1.6

²⁰ 3.2,3,4,5

²¹ 1.5

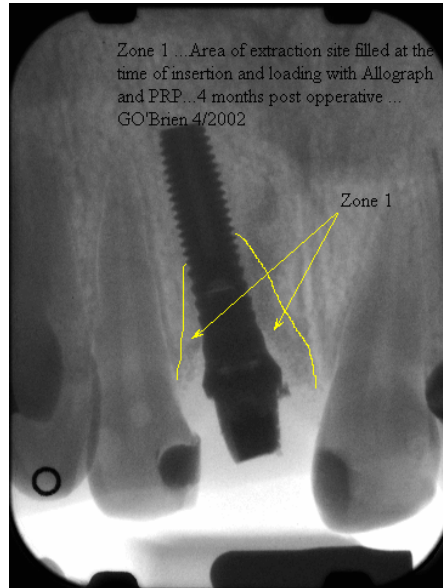
record of this change is constant and accurate because the individual pixels have no intrinsic value to each other. No change in the tissue would be demonstrated by identical pixel distribution²².

Figure 5

Digital X-ray 1.A



Digital X-ray 1.B

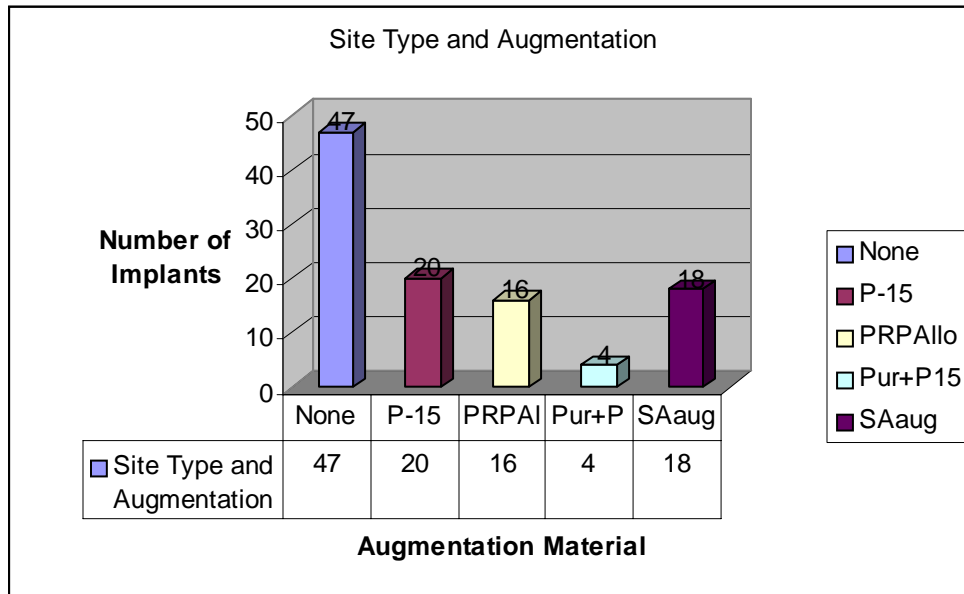


The patient selection was on a random basis due to the nature of a private practice. There was no discrimination in case selection. All procedures were based on the needs and requirements of the patient alone leading to a wide variety of applications. (Figure 3 & 6)

The program used to correlate the data and produce grafts is the Excel program by Microsoft. Each patients named is entered at the time of the placement of the SDS implant. The number of implants, position in the oral cavity, graft material used (if any), loading condition, immediate placement status, and the level of the bone relative to the coronal end of the fixture.

²² 1.5

Figure 6



Biomechanical Design and FEA of the SDS Dental Implant

Finite Element Analysis (FEA) has demonstrated that the nature of the connection as well as the properties of the surrounding bone, greatly influence stress distribution²³. Several studies have demonstrated both positive and negative influence on stress distribution based on implant geometry and diameter²⁴. The SDS dental implant was conceived from its inception with the intention of evenly distributing the stresses of occlusion away from the crest of the ridge. Observation of clinical bone loss associated with prosthetic load in various geometric configurations, of the external features, led to several conclusions: Clinical presentation of a large population of non-compliant patients that would go maintenance free for over ten years. The patient would appear with heavy calculus, severely inflamed gingival, and suppurative exudate without any radiographic or clinical signs of bone loss. Other clinical finds revealed implants that remained covered and under no load for over ten years showing no change in radiographic appearance while in this extended second stage period. These same implants after two to three years of occlusal loading many times presented with the classic “saucerization” of crestal bone loss and accompanying soft tissue sequella²⁵.

Clinical evaluation of the many different implant geometries followed a distinct pattern: One of three clinical situations were present.

²³ 7.11

²⁴ 7.12

²⁵ 4.3,4,5,6

1. There was no bone loss at the time of uncovering and no bone loss after ten years in function. In this situation very little is learned. Obviously the forces of occlusion did not exceed the limits of the given osseointegrated environment.
2. During the first three months to one year of function all the bone surrounding the dental implant progressively degenerated to ultimate failure of the implant/bone interface. There is very little learned in this situation as well. Obviously the forces of occlusion far exceeded the limitations of the osseointegrated implant/bone interface.
3. The third situation is far more interesting and informative. After the implant was prosthetically loaded, there would be a 3-6 month period of bone loss that would taper off and stop at one to two years and stay in equilibrium for up to fifteen years. Why would the bone loss start and then stop? Many times the bone would stop at the first thread. In conjunction with this observation, implants whose geometry had no threads would rarely arrest the bone loss once it had started. One would assume that sense the bone loss started, the increase in crown to root ratio would further enhance the harmful stresses of occlusion and the bone loss would progress at an exponential rate. The only explanation for this abrupt halt in bone loss after initiated, was the change in directional forces associated with the alternating tension and compression design inherent in the thread configuration. Mathematically it has been demonstrated that tensile forces introduced can be up to 5 X less that the corresponding compression counterparts²⁶. It would seem to reason that to reduce the harmful stresses at the crest of the ridge, one would be encouraged to convert these stresses to greater tensile in nature and less compression²⁷. This is accomplished by the SDS thread configuration. Looking at the mathematical derivation of stress analysis within changing thread values, the ideal angle of incidence and surface area can be extrapolated.

$$\text{(Formula 1) } \Delta \sum \chi = \Delta \sum \gamma (\frac{1}{2} \text{Sin } \alpha) \text{ O'Brien}$$

Where $\Delta \sum \chi$ is the change in the forces introduced in the surrounding bone and $\Delta \sum \gamma$ is the change in the sum of the forces of occlusion. One can see that as the angle of incidence ($\text{Sin } \alpha$), or the pitch of the thread, is increased, the corresponding transverse force into the bone ($\Delta \sum \chi$) is decreased. Using this formula the angles necessary to maximize tension at the crest and minimize compression can be derived. The distribution of stress further down the body of the fixture is also counterbalanced by the distance the stress has to travel leading to a more even stress band

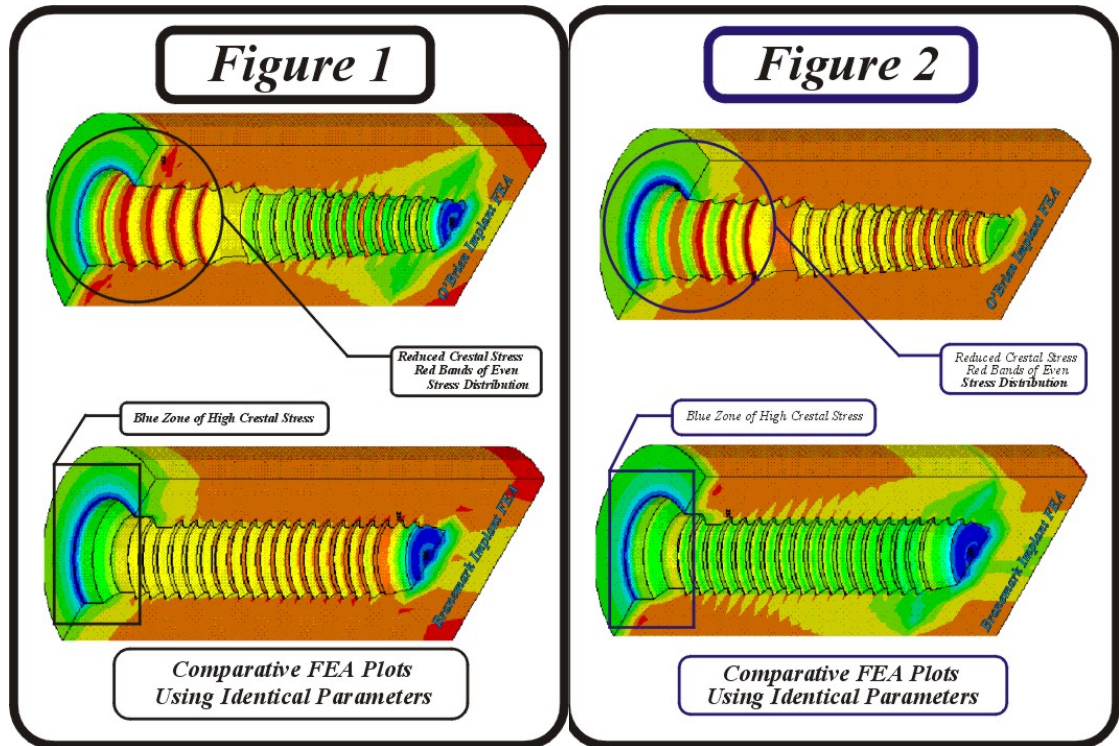
²⁶ Paper 6

²⁷ Paper 6

throughout the first 6-8 mm. This inherently would help compensate for the increased stresses associated with implant dentistry. The broader band of stress would also be more likely to yield values within that ideal zone associated with bone development and maturation. There is an ideal magnitude of stress to encourage bone remodeling and a corresponding relative magnitude of stress associated with the process of bone resorption and maturation²⁸.

FEA analysis of the SDS dental implant compared to the industry standard Branemark implant clearly demonstrates the above conclusion. (Figure 7) Clinical evidence to validate these computer-generated conclusions is the object of this study and has yet to be proven.

Figure 7



Results:

The SDS dental implant performed clinically within the published limits of other osseointegrated implants²⁹ in a variety of clinical applications ranging from conventional virgin osteotomy,³⁰ to immediate extraction and simultaneous

²⁸ 7.15

²⁹ 9.1

³⁰ 3.1

subantral augmentation under immediate loading³¹. There were 101 SDS implants recorded of which 4 were removed. This yields an initial success rate of 96%. Three of the implants that were removed were immediately placed into extraction sites # 11,13, & 15 in conjunction with subantral augmentation and immediate loading. The patient was recovering well for the first month with no complication. During the second month the patient's spouse suffered a massive stroke, which led to dietary neglect and intentional overload. Four months into the post operative care the patient developed mobility in the fixtures and the graft and temporary prosthesis was removed. It is worth noting that this patient successfully underwent the same procedure on the opposite side two years ago and the prosthesis and fixtures are clinically ideal.

The other implant that was removed was an immediate placement and loading in the position of tooth #8. This patient was a non-compliant heavy bruxer and literally rocked the fixture loose in three weeks. The implant was replaced with a two-stage procedure and completed without complication.

The early clinical and radiographic observation of the SDS implant in function is very promising. Out of the 97 fixtures still being evaluated four show some sign of early bone loss at the six month loading phase. These are implants in position of tooth numbers 30, 31, & 32. This would be consistent with reports in the literature based on the length and angulation of the fixtures alone³². All the other SDS implants are surviving without significant change. Further clinical evaluation over an extended time is necessary to make any substantial conclusion.

Discussion:

The concept of the "ideal implant design" has been a topic of great debate and study for decades. The high incidence of crestal bone loss and the associated clinical symptoms has narrowed down the qualifications. Sterile user-friendly packaging combined with ease of manipulation and handling at the time of placement, has become accepted as an industry standard with most successful systems. As computer technology and software availability exponentially progresses, biomechanical geometries derived from an enhanced understanding of the application of formulated data, has led to several unique designs and concepts. The SDS dental implant was mathematically back engineered specifically to address both surgical requirements and the un-addressed issue of crestal bone loss associated with conventional design and stress diversion. Although the helical design of the stress diversion thread was conceived in the late 1980's, a practical and consistent manufacturing protocol was only available in the late 1990's.

FEA analysis and dog studies were performed on prototype designs in the early 1990's. These studies while promising lacked the reality of human clinical trials in the everyday practice of implant dentistry. This early report and clinical trial revealed several positive conclusions regarding the market ready product:

³¹ 3.5

³² 6.2,3,4,5,6

1. The SDS dental implant is extremely user friendly with clinical success comparable to other cylindrical endosseous osseointegrated root form fixtures.
2. Packaging and delivery system is secure, stable, and sterile, lending to consistent surgical dependability.
3. The tapered “self-driving” design progressively seats the fixture to full length without requiring additional surgical steps beyond the conventional drill sequence in all qualities of bone. (i.e. no bone tap is necessary)
4. The extended “cut-out” efficiently cuts chips of autogenous bone from the site and distributes these chips into the voids within the irregular design of the helical stress diversion design. (i.e. autograph feature)
5. Prosthetic protocol is universal, accurate, dependable, and versatile for all implant born prosthetic requirements.
6. The RBM surface placed on the pure titanium surface is well received by all connective tissues and associated structures leading to secure and healthy clinical appearance.
7. The irregular thread configuration of the Stress Diversion System® integrates with the surrounding bone with the same clinical and radiographic appearance of conventional thread design.
8. Clinical observations of the SDS dental implant appear promising after one year of evaluation.

Conclusion:

Crestal bone loss and the associated clinical symptoms is an ever-growing problem in the field of implant dentistry. Attempts to prevent or minimize the incidence of crestal bone loss have led to new concepts and designs. The SDS dental implant is a cost effective change in conventional thread configuration designed to address the factors associated with the forces of occlusion that lead to crestal bone loss. While bone loss and its wake of clinical problems is a multi-factorial issue, reduction or even distribution of the harmful stresses will allow for a broader application of dental implants. Proper treatment planning and prosthetic design, close attention to good gnathodynamics, good quality and quantity of bone, and operator experience and training are just a few of the important variables necessary for a successful implant practice.

There is no expectation of total elimination of crestal bone loss by implant design alone, however, the scientific community is obligated to assist the professional with advancements in material science, education, and the application of computer assisted implant design. While the clinical evaluation of the SDS dental implant is only in its inception, the design concept will more than shift the affordable stress and bone maturation toward higher values than the conventional design.

Conclusive evidence and statements will only be available after years two and three of prosthetic loading. This paper is a prospective introduction following 13 years of research and development and should be received as such.

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