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ORIGINAL ARTICLE

Clinical osseointegration of bone level implants with conical shape and textured surface with low primary stability

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ABSTRACT

BACKGROUND: Evidence shows lower chance for osseointegration of implants without sufficient primary stability. The present retrospective study observed bone level conical screw implants with textured surface without primary stability.
METHODS: Twenty-six Stark conical screw implants, with V-Blast (Vanish Blast) surface treatment were placed with low primary stability, (insertion torque lower than 10 N/cm and visible mobility at lateral load of 250 g). A soft diet was prescribed. osseointegration was assessed applying 30 Ncm of reverse torque 6 months after placement.
RESULTS: The 26 implants that did not achieve primary stability still had a survival rate of 96% after the observation period and were classified as successful according with ICOI Pisa consensus conference success, survival, failure classification .96% of the implants showed clinical osteointegration and were successfully restored. After 12 months, all implants remained functional.
CONCLUSIONS: It can be concluded that bone-level implants with V-Blast surface in absence of functional loading are able to achieve osteointegration, even with low primary stability.

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KEY WORDS: Dental implants; Osseointegration; Tissues.

Implant stability is achieved through a primary stage of implant mechanical stabilization, and a secondary stage of biological anchorage; that is, the osseointegration process.[1, 2] Over the years, research focused on improving the ability of implants to achieve osseointegration by modifying either surface micro topography[3, 4] or implant design.[5] Implant mobility during early healing could lead to fibrous connective tissue attachment, rather than osseointegration.[6-8] Bone quality at implant insertion[9] and implant design[5, 10] are the most important factors to achieve primary stability, while surface treatment is much involved in the achievement of secondary stability.[1, 2, 9, 11] Bone quality before implant insertion can be predicted using a preoperative bone quality-density classification[9] measuring bone density through a mathematical formula that converts Houndsfields Units into measurements of bone volume. This measurement should be done only on CT scan. Rebaudi *et al.*[9] classified bone in 3 qualities: 1 Hard, 2 Normal and 3 Soft on the base of the three implant site preparation protocols available: 1 Larger drills and bone

tapping in Hard bone, 2 standard drills in Normal bone and 3 thinner drills (undersize preparation) or osteotomes technique in Soft bone. Rebaudi[9] also showed that Hard and Soft bone present more challenging situations for implant placement while Normal bone is safer. Hard bone is challenging because of its lower vascularization possibly slowing down healing processes and because it is difficult to cut, increasing the risk of bone damage due to overheating or cracking during implant site preparation and compression at implant insertion. Recent histological studies showed the dangerous effects of overheating on osteointegration.[10, 12] Soft bone also presents challenges because of its mechanical properties: bone trabeculae are very thin and may not be able to provide adequate primary stability at implant insertion.[9] Most of the implant primary stability is gained through direct contact to cortical bone, which usually represent only a superficial portion of the alveolar ridge. Thickness of the cortical bone increases in time following tooth extraction. Specifically, within a few months from extraction, cortical bone is absent or thin; however, it becomes progressively thicker (1-3 mm) in the following months and years.[13]

At the time of implant insertion, it is true that screw-type implants achieve primary stability easily, but osteointegration can also be achieved when using press-fit cylindrical implants with no threads at all.[14] Implant design, as well as shape and dimension of threads, may vary, but almost all implant systems easily achieve primary stability in hard or medium bone. On the other hand, when bone is soft, it can be very difficult to stabilize implants, irrespective of implant system.[9, 15] Soft bone has also been linked to failure of machined titanium implants.[16]

Several protocols have called for the removal unstable implants, or, when possible, their replacement with wider or longer implants to achieve the desired primary stability.[17] This indicates that primary stability remains a recurring concern among implantologists.[2, 3, 9, 18, 19] In 1998, Orenstein *et al.* reported that 3.1% out of some 2,641 implants placed were mobile after placement.[20] These mobile implants were not removed or changed, and at the time of uncovering, 93.8% of the previously mobile implants were osseointegrated. The authors compared the survival rate of implants without primary stability at placement (93.8%) to the survival rate of implants with primary stability at the time of placement (97.5%) and concluded that it might be preferable to leave unstable implants and uncover them after 4-8 months, rather than removing them and immediately substituting with longer or larger implants. Orenstein *et al.*, also suggested that the implant surface could influence osseointegration of implants without primary stability.[19, 20]

To test the hypothesis that implants unstable at insertion could achieve osteointegration with proper implant surface, the present study examined 26 such implants that presented mobility at the time of placement and had very low insertion torque.

Materials and methods

A retrospective multicenter study was performed on patients who had received Stark bone level V-Blast implants in 4 private offices.

Stark implants (Stark, Monaco) are self-tapping and designed so that the threads of the implant body which are supposed to be mainly in contact with trabecular bone have a large pitch, while the threads of the neck, that are supposed to be in contact with cortical bone, a very thin pitch. Stark implants' surface is treated with V-Blast ® (Vanish Blast), an implant surface treatment in which sandblasting is performed with a water soluble material which completely dissolves after washing in ultra-pure water and results in a peak-to-peak roughness of approximately 20-40 μm.[21]

The recommended manufecturer's surgical protocol was used for all implants and a detailed informed consent was obtained from all patients, and included in their respective charts. All patients rinsed with a 0.20% oral chlorhexidine gluconate solution (Dentosan, Recordati OTC) for 1 minute before surgery; perioral skin was scrubbed with a 4% chlorhexidine antiseptic/antimicrobial skin cleanser (ICF Clorexyderm) and then covered with sterile drapes. Local anesthetic was administered by infiltration and/or block, and a full thickness flap was elevated. A surgical guide was used to achieve ideal implant

insertion point and axis. Osteotomy drills were used in the sequence recommended by the implant manufacturer. Bone type was assessed by CT examinations before preparation of the osteotomy using the classification proposed by Rebaudi.[9] All implants were tested by applying a lateral mild load with a probe in order to verify mobility immediately after placement.

Among the inserted implants some were deemed to have not achieved primary stability, as determined by a final insertion torque lower than 10 N/cm and slight mobility of implant upon application of a lateral load of 250 g.

A 5.0 suture was used, to close the flap. When applicable, presence of mobility was reported in the chart.

After the surgery, patients were given prescriptions for analgesics (Brufen - Ibuprofene 600 mg, twice a day for 3 days) and 0.12% chlorhexidine gluconate mouthrinses. No antibiotics were prescribed. Patients were also instructed not to chew on the surgical site and not to wear their removable partial or complete dentures in the treated areas. Follow-up postoperative visits were scheduled at 1 and 4 weeks. The evaluation of the implants was performed according to the Pisa Consensus Conference classification of implant success.[22] Non-resorbable sutures were removed at the one-week postop appointment. At 4-6 months after placement a periapical radiograph was taken, a torque/countertorque test of 30 Ncm was conducted and osteointegrated implants were restored. Patients were recalled, examined, and periapical radiographs were taken for a minimum of 6 months.

Results

Between March 2016 and March 2017, 924 implants had been placed in 293 patients from 3 surgeons. Among these implants, 898 achieved primary stability, while 26 did not. A detailed description is provided for the 25 patients who had received implants with low primary stability (19 females and 6 males with mean age of 53; range 28-81). All subjects were non-smokers or smokers of less than 10 cigarettes per die and did not report any systemic disease. All implants had V-Blast surface, they were 3.7 or 4.1 or 4.7 mm in diameter and 8, 10, 11.5, 13 or 16 mm in length (Stark Iso3 Conical) (Table I). All surgical sites healed with no complications and 25 implants achieved osteointegration, while 1 failed before loading. The failed implants had been placed soft bone. No unexpected events were reported at any of the other implants. The 26 implants that did not achieve primary stability still had a survival rate of 96% after the observation period and were classified as successful according with ICOI Pisa consensus conference success, survival, failure classification.[22] No mobility, signs of radiographic bone loss, suppuration, or inflammation were present. All healed implants were stable when tested 4-6 months after placement and deemed to be osteointegrated, they were restored with no complications, and were functional 6 months after loading.

TABLE I.—*Unstable implants.*

Patient #		Gender - age	Implant diameter - length (mm)	Success after healing	Success after loading
1	12 - Soft	F - 78	3.3 - 13	Yes	Yes
2	46 - Soft	F -55	4.7 - 10	Yes	Yes
3	16 - Soft	F - 71	4.7 - 8	Yes	Yes
4	45 - Soft	F - 41	4.1 - 10	Yes	Yes
5	13 - Soft	M - 43	4.1 - 11.5	Yes	Yes
6	26 - Soft	F - 76	4.7 - 10	Yes	Yes
7	33 - Soft	F - 28	4.1 - 13	Yes	Yes
8	26 - Soft	M - 70	4.1 - 11.5	Yes	Yes
9	16 - Soft	F - 70	4.7 - 8	Yes	Yes
10	14 - Soft	M - 72	3.7 - 13	Yes	Yes
11	36 - Soft	F - 58	4.1 - 10	Yes	Yes
12	25 - Soft	F - 66	3.7 - 13	Yes	Yes
13	26 - Soft	F - 34	4.1 - 10	Yes	Yes
14	17 - Soft	M - 68	4.7 - 8	Yes	Yes
15	44 - Soft	M - 45	3.7 - 16	Yes	Yes
16	21 - Soft	F - 56	3.7 - 13	Yes	Yes
17	26 - Soft	F - 72	4.1 - 13	Yes	Yes
18	26 - Soft	F - 71	4.7 - 8	No	-
19	46 - Soft	F -74	4.7 - 8	Yes	Yes
20	14 - Soft	M - 66	3.7- 10	Yes	Yes
21	17 - Soft	F - 41	3.7 - 11.5	Yes	Yes
22	27 - Soft	F -43	3.7 - 10	Yes	Yes
23	24 - Soft	F - 81	3.7 - 8	Yes	Yes
24	44 - Soft	F - 55	3.7 - 10	Yes	Yes
25	26 - Soft	F -64	4.1 - 8	Yes	Yes
25	27 - Soft	F -64	4.1 - 8	Yes	Yes

Discussion

Successful osseointegration can be influenced by external factors disrupting the peri-implant micro-environment at implant site preparation or

during the healing phase.[1, 3, 9] This can occur as a result of physical damage during implant site preparation, biological, chemical contamination or a lack of primary stability.[3, 23-25] In this study, care was taken during implant site preparation to avoid physical damage and biological or chemical contamination, which — despite a clinician's best effort — cannot be completely excluded in hard bone, where bone heating may occur at implant site preparation because of drill friction and low vascularization of hard bone. They can, on the other side, be excluded in soft bone. Our hypothesis was that osseointegration could be achieved in soft bone, irrespective of primary stability at insertion. Among all implants inserted in the present study, only a few (2.8%) did not achieve primary stability, similarly to Dr. Orenstein's paper, which reported on 2,770 implants placed, among which 89 (3.1%) were mobile at the time of implant surgery.[19, 20]

We also found that all implants placed in hard or normal bone quality/density achieved primary stability, while implants not achieving primary stability were placed in soft bone. This finding indicates that bone quality is a strong determinant for the achievement of primary stability in agreement with Makary *et al.*[2, 3] who observed a correlation between implant insertion torque and bone density.

In the present study, 743 (80.8%) of all implants placed were inserted in hard or medium bone, while 181 (19.6%) were inserted in soft bone. Twenty-six (14.4%) of the implants placed in soft bone did not reach enough torque at insertion. A finding of the present study was that among the 26 implants inserted in soft bone 8 implants did not achieve primary stability during any time at insertion, while 18 lost primary stability and started spinning in the attempt of screwing them to final position. This finding may be useful to clinicians to increase their awareness on factors leading to poor primary stability in implants placed in soft bone. Soft bone was mainly found in the posterior upper maxillae and in sites of the alveolar ridge where teeth were recently extracted (less than 3 months). This finding is in agreement with previous studies showing that bone density is very low in the first weeks or months after extraction[26] and that delaying implant surgery in some areas of the mouth might improve stability.[9, 13] Studies indicate that a lack of stability may lead to harmful implant micromovements during the healing phase[2, 3] This phenomenon becomes evident when functional loading is applied.[2, 3, 6, 9] Szmuckler-Moncler *et al.* reported a critical threshold of micromotion (between 50 and 150 microns) above which fibrous encapsulation prevails over osseointegration[3] while Pillar reported that micromovements can be tolerated up to an intensity of 150 μm and displacements beyond that can be considered as excessive micromotion.[6]

Soft bone also lacks mechanical properties otherwise required to ensure stability at the time of insertion.[2, 3] Previous observations highlighted the fact that soft bone is at higher risk for the achievement of osseointegration, especially when early or immediate load is applied[27, 28]. For example, based on a 5-year clinical analysis on 1054 Brånemark implants (Nobel Biocare, Yorba Linda, CA), Jaffin and Berman[16] reported an excessive loss of screw implants with a machined surface in soft bone.

Some authors also suggested that implant surface may play an important role in the osteointegration of implants inserted in soft bone.[15, 17, 24, 29-31] Based on a clinical histomorphometric study, Trisi *et al.*[15] observed that a rough titanium surface dramatically enhanced the amount of bone-to-implant contact compared to a smooth titanium surface in low-density bone after 3, 6, and 12 months.[15] These results were confirmed by similar histomorphometric studies on different rough-surface treatments compared to machined surfaces.[24, 29] Histomorphometric studies and bone quality/density highlight the fact that soft bone seems to be at higher risk for implant failure since implants inserted in soft bone often show lower torque levels, higher failure rate and, sometimes, mobility immediately after insertion.[9, 15, 24, 29] The results of the present study confirm these histomorphometric studies on rough implant surface[15, 24, 29] since showed that a high percentage of implants lacking primary stability successfully osseointegrated at the end of the healing period.[32] Thus, the surface of implants inserted with low insertion torque into soft bone may help acquiring secondary stabil-

ity, *i.e.*, osteointegration, even in the absence of primary stability.

The present study observed that implant design does not always guarantee implant stability in soft bone, allowing us to reject the null hypothesis and affirm that a high rate of successful osteointegration was achieved in these cases as a direct result of surface treatment, providing secondary stability, even if primary stability was lacking. Therefore, this finding is in agreement with that of Orenstein *et al.*[20] who found that all Hydroxyapatite-coated (HA) implants were mobile at placement, but still achieved osteointegration. On the contrary, only 81.5% of the mobile non-HA-coated implants obtained osteointegration. Based on this finding, the authors concluded that it might be preferable to leave implants with a rough surface treatment in their mobile state at placement, uncovering them after 4-8 months, rather than taking them out and substituting larger implants.[20]

Similar findings were found in a subsequent study published by the same authors.[19] Of 2,770 implants placed, 89 (3.1%) implants were mobile at the time of implant surgery.[19] These mobile implants had a lower survival rate of 79.8%, when compared to implants that achieved primary stability with a survival rate of 95.9%. They also found that implant surface might play an important role in osteointegration of unstable implants since Hydroxyapatite-coated implants had an increased survival rate when compared to machine-surfaced implants (92.8% *vs.* 53.6%). Comparing the present study with that of Orenstein, differences involve implant number, survival rate and different implant types and surface treatment, *e.g.*, HA-coated *vs*. V- Blast. Thus, the higher success rate of the present report could have resulted from the obvious limitation of our study with respect to the small patient cohort, which prevented statistical analysis, but also from the relatively short time period between placement of restorations and last evaluation (6 months after loading observation time). However, this analysis still shows success with mobile implants and contradicts the notion that primary stability must be achieved at implant placement in order to ensure implant success. Recent studies clarified the important role of implant displacement and micromotion during immediate and early healing, highlighting the importance of the effects of functional loading directly or indirectly applied on implants.[27, 33-36] These studies along with the results of the present study indicate that low primary stability may not be as influential to implant failure as previously thought, if implant micromotion is low and implant surface osteoconductive. Future research will attempt to prospectively following a larger number of mobile implants for a longer period of time after placement, as well as using more objective measurements when classifying the degree of mobility.

Conclusions

The present study observed that V-blast surface implants with low primary stability successfully osseointegrated with a 96% success rate after which they seemed to be indistinguishable to implants placed with higher primary stability. Further investigation is necessary to investigate the role of different implant surface treatments to successful osseointegration in implants placed with low primary stability.

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