Quality of implant surfaces and poor osseointegration

Part II: Irregular surface roughness suspected of causing deficient osseointegration

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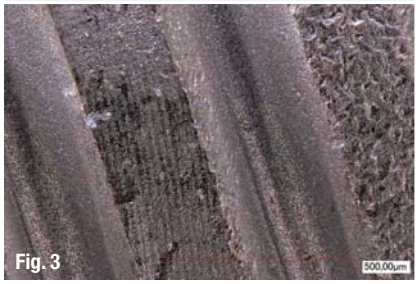
Fig. 1_Implant #001 (SLA M-line) at 30× magnification: irregularities in the surface roughness are evident.
Fig. 2_Implant #001 (SLA M-line) at 100× magnification: there are parts on the crestal implant body with sanding marks and no surface treatment.
Fig. 3_Implant #001 (SLA M-line) at 300× magnification: structural defects due to blasting media and massive residue are evident.
Fig. 4_Implant #002 (SBA M-line) at 30× magnification.

_**Modern dental implants** are made of a titanium alloy or a combination of titanium and ceramic. Pure titanium implants are also still manufactured. Titanium induces bone on-growth through a direct biochemical interaction with bone tissue. The biological response of the organism is related to the formation of a titanium dioxide layer, as discovered by Per-Ingvar Brånemark and widely applied to orthopaedic treatment.

Besides this natural response to titanium, a series of other factors enhance bone tissue on-growth, even ingrowth, as in porous tantalum implant surfaces. Surface roughness, macro- and microstructure, as well as pores and specific laser configurations, increase bone–implant contact (BIC), offering more surfaces for osseointegration and stability under occlusion. All of these parameters are important characteristics of implant surfaces. The rate and speed of osseointegration, as well as the time of loading, correlate with the texture and quality structure of such surfaces.



Several studies claim, controversially, that in the first year after loading implants show a vertical bone loss of approximately 1 mm and another 0.2 mm for every year thereafter. Such claims, although they do not consider implant type and design, soft-tissue quality, operation protocol, abutment connection, etc., have been accepted as true nonetheless by the industry. Currently, operators consider such findings not critical.

The industry has had different responses to this problem. Some manufacturers focus on the abutment–implant connection, others on the crestal implant design or implant collar surface, and yet others on platform switching and crestal or sub-crestal implant placement. The elimination of microgaps, the improvement of peri-implant tissue quality and quantity through platform switching, the reduction of bone stress through reduced roughness crestally or specific laser-directed thread design partially solve the bone loss problem.

Hybrid implants are the most recent trend in oral implantology. Manufacturers claim reduced bone stress and pressure, better hygiene, long-term tissue stability through lack of inclined threads, a better tissue response, reduction of the risk of peri-implantitis, faster integration and many other all-in-one solutions.

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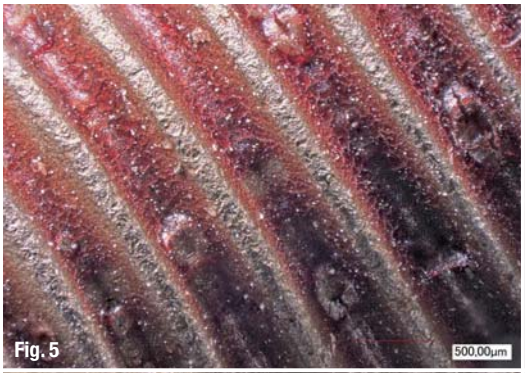
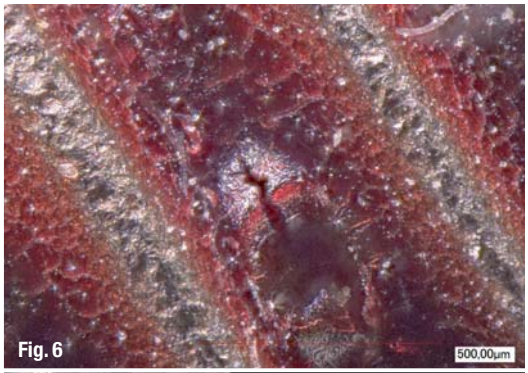
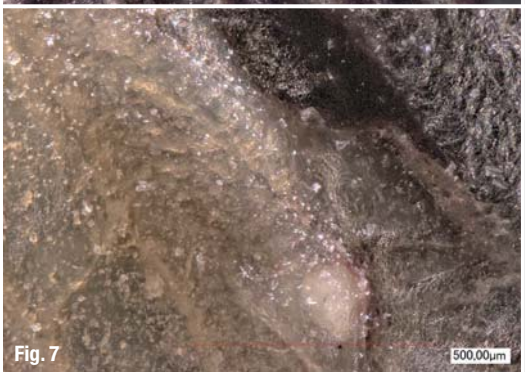
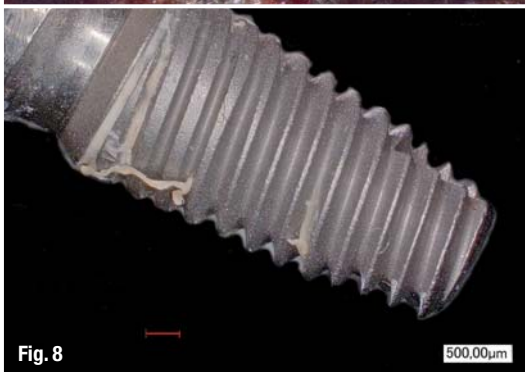
Fig. 5_Implant #002 (SBA M-line) at 100× magnification.
Figs. 6 & 7_Implant #002 (SBA M-line) at 300× magnification.
Fig. 8_Implant #007 (ZBM) at 30× magnification.









All of these features offer advantages and help eliminate some risks. Tissue response, however, cannot be influenced massively. Universal laws underlie the biological response; so structures smaller than 5 µm are not detectible from osteoblasts. Other studies have shown major advantages of a roughness depth exceeding 100 µm. However, roughness depths of less than that affect functional integration and cellular apposition negatively.

It is reasonable to deduce that implant design, thread design and all macrostructural features only increase primary stability and promote integration until the organism begins to form new bone, six weeks after bone trauma. The BIC ratio is an important guideline. Softened implant surfaces reduce the BIC ratio if not detected at the cellular level. The results are similar if the BIC ratio is reduced through irregular surface roughness, structural defects or debris on the implant surface.

_Study presentation

In this study, we examined six failed implants (from 16 lost in total), comparing them with six identical sterile-packaged ones. The other ten failed implants were reclaimed. All of the examined implants were from the same manufacturer. The fabrication numbers of the failed implants correlated to that of the packaged ones. In this part of the series, we examined the implant macroscopically, up to 300× magnification under a light microscope. A similar or identical clinical finding was made for all of the failed implants.

The implants had two different surface types, one blasted with zirconium dioxide particles and one sand-blasted and acid etched. The implant body design was identical in all, with two different collars, one machined and one textured at bone level. The implants with a machined collar received at the crestal third only double etching.

The examination sought to answer the following questions:

1. Are there production faults or residue on the surface of the sterile implants?
2. Are there structural defects or irregularities on the surface of the sterile implants?
3. Are the specifications and labelling of the manufacturer correct and detectable?
4. Are there defects, irregularities, residue or other abnormalities on the surface of the explanted implants?

After the implants had been placed following standard protocol, re-entry occurred after four to five months postoperatively. Screwing in the impression post (implant #005) or the abutment (implants #002 and 005; Figs. 4–7) led to complaints. The patients described it feeling as if the implants had been placed deeper into the bone osteotomy. In the case of implant #005, the impression was nonetheless successful. Implant #002 was loaded as planned. Implants #006 and 008 received prostheses as planned (see Part I of this series in implants 2/15). All of the failed implants were removed within two weeks of loading. The reverse torque needed did not exceed 5 Ncm.

No	Region	Surface	Bone density, Misch CE, 1990	bone volume Misch CE, 1990	Exposure, Tal H., 1999	Surgery	GBR	Prosthetics planed, Misch CE, 1991
1	16	machined collar	D2	A	0	Conventional	none	FP-2
2	45	machined collar	D3	A	1	Conventional	none	FP-1
3	16	textured collar	D3	C-h	0	Guided	ext. sinuslift	FP-2
4	44	textured collar	D2	A	0	Guided	none	FP-2
5	33	textured collar	D2	A	0	Conventional	none	RP-5
6	15	bone level zikronia blasted	D3	C-w	0	Conventional	lateral	FP-1
7	43	machined collar	D2	A	0	Conventional	none	RP-5
8	15	bone level zikronia blasted	D3	C-h	0	Conventional	int. sinuslift	FP-1
9a	46	bone level zikronia blasted	D2	A	1	Conventional	none	FP-1
9b	36	bone level zikronia blasted	D2	A	0	Conventional	none	FP-2
9c	34	bone level zikronia blasted	D3	C-h	0	Guided	gap to buccal plate	RP-5
9d	32	bone level zikronia blasted	D3	C-w	0	Guided	none	RP-5
9e	42	bone level zikronia blasted	D3	C-w	1	Guided	none	RP-5
9f	15	bone level zikronia blasted	D3	B	0	Conventional	none	RP-4
9g	11	bone level zikronia blasted	D3	C-w	0	Conventional	gap to buccal plate	RP-4
9h	21	bone level zikronia blasted	D3	C-w	1	Conventional	gap to buccal plate	RP-4
10	–	machined collar	–			–	–	
11	–	bone level zikronia blasted	–			–	–	
12	–	textured collar		Sterile packages, controll group		–	–	
13	–	bone level zikronia blasted	–			–	–	
14	–	machined collar	–			–	–	

Tab. 1_Specimen classification of surgical and prosthetic planning.

All of the implants had shown similar radiographic findings: lack of osseointegration at the crestal third and crater-like vertical bone resorption in some cases. These findings were unexpected, taking into consideration that no complications had occurred during treatment. In some cases, patients had received implants from other manufacturers on the contralateral side and these were functioning as expected. After explantation, none of the osteotomies showed soft-tissue ingrowth. Also, regions that had been augmented showed no bone loss or wall defects. Based on these findings, we decided to replace all of the explanted implants but #006 and 008 (the first two failed implants) immediately with implants from different manufacturers. In all of the cases, the patients received prostheses after three to four months and the surgical and prosthetic treatments were successful.

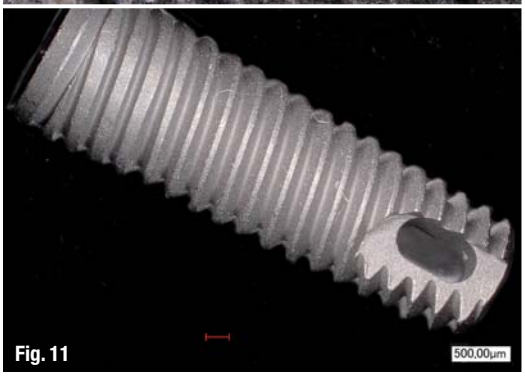


Fig. 9_Implant #007 (ZBM) at 100× magnification.
Fig. 10_Implant #007 (ZBM) at 400× magnification.
Fig. 11_Implant #0011 (ZBM Kontr.) at 30× magnification: bone-level implant, blasted and not etched.
Fig. 12_Implant #0011 (ZBM Kontr.) at 100× magnification: the surface appears rather metallic.

_Materials and methods

All of the patients in this study received more than one implant. Some of them lost more than one, and implants with the same fabrication numbers failed in all of these patients. While ten implants where reclaimed, six explanted implants were compared with six sterile-packaged ones of the same fabrication number. All of the examined implants were analysed under a light microscope at a magnification of 30× to 300×. The packaged implants were thoroughly checked in terms of accuracy of the information on the packaging.

The following implant regions were examined under the microscope:
- implant collar, swift to threads
- middle of implant body with trapezoidal thread, swift to triangular threads
- apical of implant body, sharp triangular cutting threads
- suspicious regions on the explanted implants
- regions showing evident defect under minimal magnification
- regions with no evident bone on-growth
- regions with tissue residue.

_Results

Implants #001, 0014, 0015, 002 and 007

Implant #001, correlating to #002, showed massive surface defects, especially on the thread crest. At 30× magnification, irregularities in the surface roughness were evident. A hybridity of the roughness was not detectible. At 100×, parts on the crestal implant body with sanding marks and no surface treatment were observed. At 300×, structural defects due to blasting media and massive residue could be seen. Besides production faults, there was a reduced and irregular roughness. We also made findings that could not be specified, but that included artificial and faulty defects (Figs. 1–10).

Implants #0011, 0013 and 006

Implant #0011 was only blasted and not etched. It was a bone-level implant. Apart from blasting media residue covering the whole implant body, we detected metal cuttings. The presence of such cuttings could be explained as being due to deficient cleaning procedures and poor quality control, since such contamination was apparently not detected. Generally, the surface appeared rather metallic. Reflection electron microscopy would help determine micro-roughness (Figs. 11–13).

Implants #0012, 003, 004 and 005, correlating to #17, 18 and 19

These implants exhibited a more precise thread design and surface treatment. The metallic lustre of the surface and the major blasting media defects on the crest of the threads were prominent. The thread flanks showed no macrostructure, so we found also in these implants an irregular surface roughness. The most serious issue in this group was the labelling of the implants as bone level although the implants had a machined collar inside (Figs. 14–16).

Bone-level implants with platform switching are placed differently to implants with a machined collar.

No	Region	Surface	Re-entry months post OP	Failure manifestation	Symptoms	Explantation socket	Follow treatment
1	16	machined collar	4	By cover screw removal implant rotated	Pain by unscrewing cover screw	No soft tissue ingrowth, no inflammation symptoms	immediate implantation, different manufacturer, similar diameter
2	45	machined collar	4	Crown rotation 2 weeks after loading	Pain on function	No soft tissue ingrowth, no inflammation symptoms	late implantation, different manufacturer, similar diameter
3	16	textured collar	5.5	Reverse torque 5 Ncm	Pain by unscrewing cover screw	No soft tissue ingrowth, no inflammation symptoms	late implantation, different manufacturer, similar diameter
4	44	textured collar	5.5	Reverse torque 5 Ncm	Pain by unscrewing cover screw	No soft tissue ingrowth, no inflammation symptoms	late implantation, different manufacturer, similar diameter
5	33	textured collar	4	Crown rotation 2 weeks after loading	Pain on function	No soft tissue ingrowth, no inflammation symptoms	immediate implantation, different manufacturer, similar diameter
6	15	bone level zikronia blasted	4	Crown rotation 2 weeks after loading	Implant rotation after removing neighbour implant	No soft tissue ingrowth, no inflammation symptoms	late implantation, different manufacturer, similar diameter
7	43	machined collar	4.5	Reverse torque 5 Ncm	Pain on function	No soft tissue ingrowth, no inflammation symptoms	immediate implantation, different manufacturer, similar diameter
8	15	bone level zikronia blasted	4	Crown rotation 2 weeks after loading	Implant rotation, occlusion	No soft tissue ingrowth, no inflammation symptoms	late implantation, different manufacturer, similar diameter
9a	46	bone level zikronia blasted	3.5	By cover screw removal implant rotated	Pain by unscrewing cover screw	No soft tissue ingrowth, no inflammation symptoms	immediate implantation, different manufacturer, similar diameter
9b	36						
9c	34	bone level zikronia blasted	3	Abutment rotation 2 weeks after loading	Pain on function 2 weeks after loading	No soft tissue ingrowth, no inflammation symptoms	late implantation, different manufacturer, similar diameter
9d	32						
9e	42						
9f	15						
9g	11		4				
9h	21						
10	–	machined collar	–			–	–
11	–	bone level zikronia blasted		Sterile packages, controll group		–	–
12	–	textured collar	–			–	–
13	–	bone level zikronia blasted	–			–	–
14	–	machined collar	–			–	–

Tab. 2_Clinical findings.

They are placed sub-crestally, while implants with a machined collar are always placed above crestal bone. Proper quality control would have prevented such an error. Of course, erroneous labelling is not necessarily problematic regarding osseointegration; it is irritating.

_Discussion

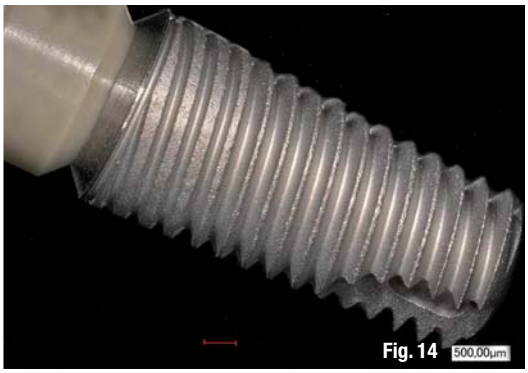
The clinical and radiographic findings did not explain the deficient osseointegration adequately. Inaccuracies and irregularities of implants cannot promote integration. Combined with residue, impurities

No	Region	Surface	irregular roughness	irregular surface, partly no surface treatment	blast defects	blast media residuals, massiv	metal cuttings	undefined structural defects	compromised tissue ongrowth	dokumentation fault
1	16	machined collar	yes	no	yes	yes, massiv	–	yes	apical third, only thread flanks	no
2	45	machined collar	yes	no	yes	yes, massiv	–	yes	apical third, only thread flanks	no
3	16	textured collar	yes	no	yes	yes, massiv	–	no	crestal third	no
4	44	textured collar	yes	no	yes	yes, massiv	–	no	crestal third	no
5	33	textured collar	manufacturer	manufacturer	manufacturer	manufacturer	manufac-turer	manufacturer	manufacturer	manufacturer
6	15	bone level zikronia blasted	no	yes	yes	yes, massiv	–	yes	barely, only thread flanks	no
7	43	machined collar	yes	no	yes	yes, massiv	–	no	crestal third	no
8	15	bone level zikronia blasted	manufacturer	manufacturer	manufacturer	manufacturer	manufac-turer	manufacturer	manufacturer	manufacturer
9a	46	bone level zikronia blasted	manufacturer	manufacturer	manufacturer	manufacturer	manufac-turer	manufacturer	manufacturer	manufacturer
9b	36									
9c	34									
9d	32									
9e	42									
9f	15									
9g	11									
9h	21									
10	–	machined collar	yes	yes	yes, major	yes, massiv	no	no	–	no
11	–	bone level zikronia blasted	no	no	yes	yes, massiv	yes	no	–	no
12	–	textured collar	yes	no	yes, great	yes, few	no	no	–	M-Line inside
13	–	bone level zikronia blasted	yes	no	yes	yes	–	no	–	no
14	–	machined collar	yes	no	yes	yes	–	no	–	no

Tab. 3_Findings light microscopy.

and production faults, this results in the deficient performance of such workpieces and under certain circumstances in a poor tissue response, such as isolation or encapsulation. Most important are the reduction of BIC and increase in the time tissue needs to overcome obstacles, if possible. The microscopy findings confirmed our initial suspicions (see Part I of this series). They determined a number of factors that influence tissue response and osseointegration. The findings were as follows:

- blasting media residue
- surface defects
- lack of surface treatment
- lack of thread precision
- production procedure residue
- metal cuttings



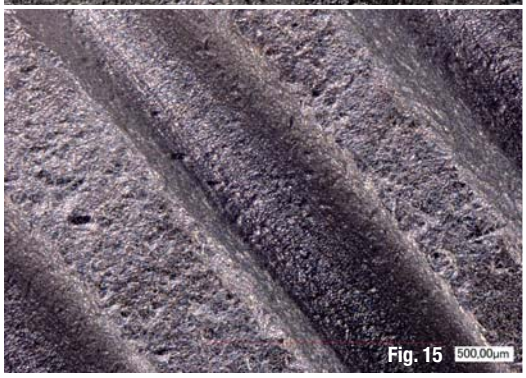


Fig. 13_Implant #0011 (ZBM Kontr.) at 300× magnification.
Fig. 14_Implant #0012 (SBA B-line) at 30× magnification.
Fig. 15_Implant #0012 (SBA B-line) at 100× magnification.
Fig. 16_Implant #0012 (SBA B-line) at 300× magnification.

– irregularity in surface roughness
– faulty labelling
– deficient quality control.

For patients who had lost more than one implant, only one implant was analysed by the authors. The other failed implants were sent to the manufacturer for further analysis. At the time of writing, we had received no feedback from the manufacturer.

_Conclusion

Today, we understand the mechanism of osseointegration. The implant design ensures primary stability. After the tissue response has been initiated, new bone formation takes place after six weeks. From this point, the implant design is irrelevant. Only the implant surface, microstructure, porosity, texture and cleanliness influence further biological processes. A great thread pitch placed in D1 or D2 bone quality and great augmentation volumes demand longer healing periods.

Other design features are only important for long-term stability and can be an issue after loading the implants (emergence profile, platform switching, soft-tissue quality and quantity). Morphology, alignment and texture of crestal options, abutment connection and platform switching complete the scaffold for successful hard and soft-tissue stability. Bone formation and remodelling cannot be accelerated, and underlying natural biological processes are completed after six months postoperatively.

Users expect the perfect performance of the products with which they treat their patients. In the third part of the series, we will examine the current specimens under an electron microscope. Additionally, we will examine failed and sterile-packaged implants from another two manufacturers, comparing the precision of thread design, production residue, tissue ongrowth on the surface and surface defects._

Editorial note: Editorial note: The authors receive no financial incentive from the manufacturer. All of the implants were purchased. The failed and sterile-packaged implants originated from three different private practices.

The implant fabrication numbers and literature can be requested from the publisher.

contact

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