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RESTORATION OF TWO PATIENT CASES WITH SCREWABLE BASAL IMPLANTS (BCS) FOLLOWING FAILURE AFTER LATERAL BASAL AND CRESTAL IMPLANTS MADE FROM A PEEK-COMPOUND¹.
CASE DESCRIPTIONS AND FAILURE ANALYSIS.

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Contact

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The Foundation of Knowledge

Restoration of two patient cases with screwable basal implants (BCS) following failure after lateral basal and crestal implants made from a PEEK-compound¹. Case descriptions and failure analysis.

Authors:

Prof. Dr. Stefan Ihde
 Head of Dental Implants Faculty
 Intl. Implant Foundation
 Leopoldstr. 116
 DE-80802 Munich/Germany
 drsihde@ihde.com

Dr. Antonina Ihde
 MNE-85315 Vrba/Tudorivici
 Montenegro
 antonina.ihde@gmail.com

Abstract

This article describes problems which occurred with a specific type of lateral basal and crestal implants and analyses a number of likely causes of their failure. The implants under discussion here were made from a PEEK-compound (Polyetheretherketone/BaSO4 6 %).

According to our analysis the failures are closely connected to the design of the

implants, combined with the specific choice of the implant material and mistakes in the clinical application of the implants and the prosthetics.

Keywords: Basal implants, modified PEEK-compound, iso-elastic design of dental implants, immediate loading, osseo-integration.

1. Introduction

In search of the isoelastic material being compatible with the flexion of bone polyaryletherketone (PAEK) polymers got introduced in the field of orthopaedics, traumatology and dentistry. Polyetheretherketone (PEEK) is demicrystalline thermoplastic, and it is being used and studied extensively due to its potentially "iso-elastic" and thermoplastic properties. The work-pieces are inherently strong, inert and biocompatible and made the greatest clinical impact in the field of spine implant design.

In this report we describe the necessary corrective intervention in two patients which had received treatment with a specific type of plastic implants. A 45-year old female (patient 1) healthy patient, non-smoker, and a 46-year old healthy male patient (patient 2), non-smoker, requested advice after recurrent complications with the implants in the upper jaw had taken place. The panoramic overview radiograph of both patients revealed massive osteolytic areas around four lateral basal implants in the upper jaw, Figs. 1 and 2. The implants had been equipped with prosthetics in an immediate load protocol within a few days post-operatively. Later several surgical corrections had been undertaken, but the problems (chronic infection, pain, mobility) persisted.

¹ Perso-C and Perso-B implants. Supplier: F.-P. Spahn Genkersteenweg 470, BE-3500 Hasselt, Belgium. Perso-C, Perso-B, and Sisomm are registered trade-marks of Victory-med n.v., Heidestraat 99, 3581 Beverlo, Belgium

After being under treatment for about 1.5 years totally, the patients requested a second opinion and attended our clinic, where the corrective intervention was performed.

2. Material and Methods

Patient 1:



Fig. 1: Pre-operative panoramic overview of both jaws of patient 1. Massive osteolytic areals around all PEEK-compound implants in the upper jaw are well visible. The cortical border to the maxillary sinus floor is missing on both sides. The crestal PEEK-compound implant in area 44 shows a circumferential translucency, indicating that the implant is not integrated. Nevertheless the bridge showed only a Grade 1 clinical mobility.



Fig. 2: Panoramic overview on both jaws of patient 1 after removal of Perso-B® implants from patient 1, and placement of screwable basal implants. The remaining PEEK-implant in area 45 shows circumferential translucency, however the patient postponed the removal of this implant for the time being. The well integrated 2-stage-titanium implant in area 14 was included into the new construction.



Fig. 3: Panoramic overview of both jaws after equipment of the freshly placed basal screw implants with fixed metal-to-ceramic bridges, 2 days post-operatively.



Fig. 4: Zirconium bridge on 2 lateral basal PEEK-compound implants and one crestal titanium implant in area 14. The bridge shows grade 1-2 mobility and was fixed rigidly only at the implant 14 (Patient 1).



Fig. 5: Sectioning of the zirconium bridge in the area of the crestal implant 14. After sectioning the whole bridge appeared very mobile (Grade III+ Mobility, both vertically and laterally, Patient 1)

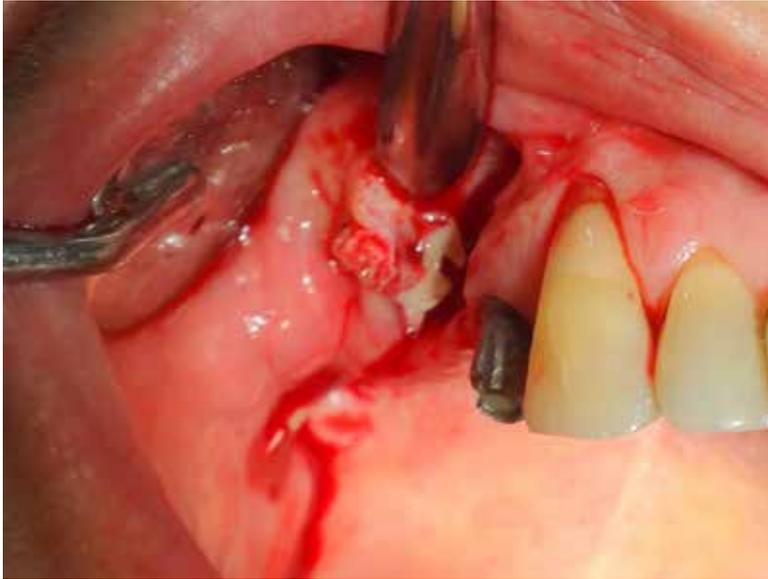


Fig. 6: Removal of the lateral basal PEEK implant out of granulation tissue in the upper jaw. (Patient 1)



Fig. 7: Direct view in to the open sinus after removal of the lateral basal PEEK implant. (Patient 1)

In local anaesthesia all PEEK-compound implants were explanted and the granulation tissue around them was removed. The implants had not been integrated at all. On both sides the sinus showed openings of the bony floor of about 7x7mm.

Patient 2:

In local anaesthesia all three affected segments received a corrective intervention, with the implants being removed and replaced.



Fig. 8: Pre-operative radiographic overview on both jaws of the male patient with a number of PEEK-compound implants in upper and lower jaw:

- segment on 2nd premolar and one lateral basal implant and a crestal PEEK-compound-implant in the tuberosity region (upper right side). Severe bone loss along both PEEK-compound implants. The lateral-basal PEEK-compound implant seems not to be in contact with the bone at all. Prosthetics: zirconium-to-ceramic bridge.
- segment on 1st premolar and two lateral-basal PEEK-compound implants with bone loss all around the base plates of both implants (upper left side). Prosthetics: zirconium-to-ceramic bridge.
- Bridge from the 2nd premolar to a crestal PEEK-compound implant in area 36 (lower right side). Prosthetics: crown on 45, bridge to the implant, zirconium-to-ceramics.



Fig. 9: Post-operative panoramic overview picture of both jaws after the removal of the PEEK-compound implants and replacement by screwable basal implants and loading within 3 days. The apical part of the Perso C[®] implant was left inside the mandible. In the lower jaw the Perso C[®] was removed only partially. Although it was highly mobile it was interlocking in the basal cortical bone. The 3rd quadrant was equipped with a KOS- implant and a BCS-Implant in an immediate load protocol.

3. Results

3.1. Patient 1

Both segments in the upper jaw were equipped with screwable basal implants (BCS) and cemented metal-to-ceramic bridges. On the right side the remaining 2-stage-implant (unknown brand) was included into the new construction. The distal anchorage was created through tubero-pterygoid screw implants, Fig. 3.

3.2. Patient 2

All three segments were equipped with screwable basal implants and cemented metal-to-ceramic bridges thereon. Due to the severe lack of bone the stability for the bridge in the upper left segment was gained through a BCS

3.6 x 26mm implant, which was anchored in the cortical floor of the nose. The distal anchorage was created through tubero-pterygoid screw implants. Fig. 9.

4. Discussion

4.1. Properties and design of PEEK-compound implants

Lateral basal implants are designed to anchor at least in two corticals, i.e. either the lingual and the vestibular cortical or the palatal and the vestibular cortical.

From this point of view the lateral basal PEEK-implants under consideration here could theoretically be well suited as dental implants.

In the daily practice the implants under

consideration here are however unsuitable and there are a number of good reasons for this statement:

- lateral basal implants might work well if the base plate is hidden deep in the bone, and far away from the mucosal penetration to the contaminated oral cavity. In such indications any screw implant would work also. The main indications of lateral basal implants are regions with reduced vertical bone supply. If applied in exactly these cases PEEK lateral basal implants may cause severe problems such as massive osteolysis.
- The manufacturer has designed the implant to be adjusted in size during the operation. At first glance this seems a very clever solution, because the implantologist manages with one size of implants only and he can trim the implant down to the desired diameter. In the clinical reality this solution is connected to a number of unacceptable disadvantages:
 - a.)** If the implant is trimmed during the operation the surface remains contaminated with small chips of particle which cannot be removed safely. These particles may lead to granulation and propagate infections. A validated intra-operative cleaning procedure for implants does not exist.
 - b.)** As a result of the trimming the load transmission areas are reduced in an uncontrolled way. Earlier investigations have shown, that the amount of load transmission surface of the lateral basal implant on each side of the vertical implant part, i.e. the distribution of masticatory forces on each

of the engaged forces are critical for its success (2).

c.) An extremely critical point is however the fact, that after the intra-operative trimming sharp edges result on the baseplate. These sharp edges will inevitably lead to localized overload osteolysis under function, and in addition they may lead to penetrations of the oral mucosa and subsequently to infections of the implant bed. Fig. 10 shows four lateral basal implants made from PEEK after removal.

d.) Finally it can be stated, that the holes in the base plate are presumably too small to allow bone growth through the holes. This growth is necessary to allow full integration of the implant into the bone, including functional load transmission of masticatory forces.

e.) Also for mechanical reason it is not advisable to trim parts made from PEEK, because the long molecule chains align in the mould during the process of injection of the material under heat. If these chains are later trimmed, the mechanical properties of the material suffers automatically. They become non-defined.



Fig. 10: Four lateral basal implants made from modified PEEK after removal out of massive granulations in patient 1, upper jaw. Note that the implants were inserted exactly in the shape as shown here. It was not necessary to cut anything off from the implants during the removal, as they were not osseointegrated at all. Hence the surgeon had trimmed these implants in this way.

It is known that implants made from PEEK show a significantly lower bone-to-implant contact (BIC) compared to implants made from titanium or titanium alloy (1). This leads to the necessity to safely engage the base plate into corticals, as these parts of the bone show a higher tendency to heal and thereby integrate the implants. Note that all dental implants should at least allow the active biological integration of the endosseous (central) parts of the implants into the bone. The implants under discussion here do not allow this integration especially in case with reduced bone height.

- an implant which is by design determined to be applied in sites with reduced bone heights (i.e. lateral basal dental implants), must be suitable for application in reduced bone heights under all aspects. If this is not the case, it must be considered a potential danger.

The manufacturer of the dental implants under discussion here claims, that PEEK (-compound) as an implant material is extremely advantageous, because the material is “iso-elastic”, i.e. the Modulus of Elasticity of the material is near to that of “the bone”. At the first glance this argument seems to be of high

significance. When looking closely on the related facts, the theoretical “advantage” disappears however: as shown in Table 1, cortical bones show, depending on the clinical use quite different mineral contents and thereby extremely different moduli of elasticity. For this reason it is possible to successfully integrate dental implant made from Titanium or Titanium-Alloy into all bones of the human body.

Variable	Elk Antler	Cow Femur	Whale Bulla
Fracture Resistance, J/m ²	6190	1710	200
Flexural Strength MPa	247	179	33
Elasticity mod., GPa	7.4	13.5	31.3
Acoustic impedance	3.75	5.27	8.79
Mineral content	59.3	66.7	86.4

Table 1: Comparison of different mechanical parameters and their relationship to the mineral content in different cortical bones (3). Note that, for example, a 45 % increase of the mineral content of cortical bone leads to a 4.2 fold increase of the Modulus of Elasticity. The bone of human jaws resembles nearest the cow femur.

During the first phase of integration of lateral basal implants the peri-implant bone softens as a result of the increase per-implant remodeling (4, 5). This allows a gradual adaptation of the bones mineral content to the stiffness of the implant. During this healing process the basal implants are rigidly anchored in the cortical bone. To allow integration into the bone the implant body itself must be rigid and not elastic. An implant whose body visibly deforms

under normal masticatory load, will presumably not integrate under immediate load conditions. Such implants may theoretically integrate after the bone has healed and corticalized around the unloaded endosseous implant parts, thereby taking over a stabilizing function. It has been described in literature that elastic implant bodies in general cannot integrate successfully, because the implants deform under the masticatory forces and create local intra-bony stress

peaks and subsequent osteolysis (6). Elastic implant designs do not provide a defined amount of load transmitting interface, because only a part of the surface participates in the load transmission while other parts of the implant are shielded from forces while deformation takes place.

When searching the literature about PEEK dental implants, only a few citations are found. The treatment descriptions of Karan et al. (7) reveals besides a very good background description also two excellent radiographs, which show

that dental implants from PEEK do integrate well if the design of the implant is chosen properly, however in their case descriptions a number of inconsistencies have to be mentioned: Karan et al connected an implant made from pure PEEK to an implant made from Titanium or Titanium alloy (Figs. 11, 12 and 13 were taken from article (7), with permission of the authors). Thereby the “elastic” properties of PEEK were probably extinguished and the whole bone-implant-prosthetic system behaved stiffly, at least more stiff than bone.



Fig. 11: A stable design of a PEEK implant, as used and described by Karan et al (from Ref. 7)

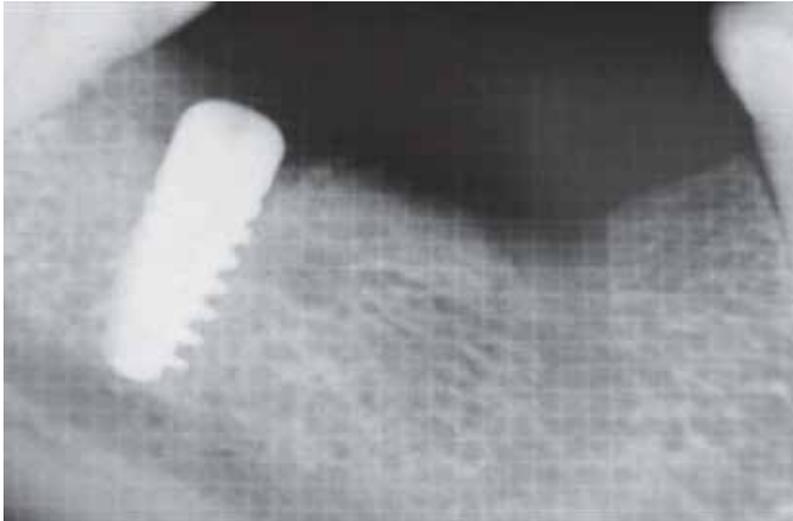


Fig. 12: PEEK implant post-operatively in area 46, Titanium implant in area 47 (from: Ref. 7)



Fig. 13: Corticalisation around the PEEK implant in area 46 reveals good integration of the implant including load transmission at the interface to the bone (from REF 7). In this application elastic properties of the material presumably do not play a large role, because the bridge and the other implant are rigid and the bridge-span is small. The titanium implant shows little crater-like crestal bone loss. The PEEK-implant is not visible and therefore such bone loss, even if it had occurred, could not be diagnosed.

All “Perso C” implants observed in the patient cases described here showed in all locations on both cases a completely different way of integration (Fig. 14).



Fig. 14: CT-scan of the Perso-C-implant in area 47 from patient 2. Only the most apical part of the implant seems integrated, while the upper part of the implant is very mobile inside the bone and lacks osseo-integration. This situation was found in all Perso-C-implants in both patients. No cortical integration (Extra-territorialisation) was observed along the vertical axis of the PEEK-compound implants.

4.2. Analysis of manufacturer’s product claims

In a prospectus the manufacturer claims a number of product advantages which will be analysed now:

Claim 1: “Elasticity and physical properties similar to bone.” and “The deformation under stress is similar to the jaw bone deformation.”

This claim is misleading and it is simply wrong, because the Modulus of Elasticity of PEEK-compound is near 4.2 GPa (“PEEK Optima”), while human bone reaches around 13-18 GPa, Table 1.

In the clinical reality bone adjusts its elasticity and mineral content and thereby its elasti-

city according to the mechanical demand and hence shows a wide variety of physical properties. An adjustment “down” to 4.2 GPa seems impossible however, such tissue would not be bone any more and could not perform as a jaw bone. Especially after successful osseo-integration bone adjusts the mineral content in the vicinity of the implant, a phenomenon which was also called “Extra-territorialisation” by Donath, and “Osseo-integration” by Branemark. Recently science seems to have an altered view on the reasons of bone loss and increases in mineralisation (10).

In the cases shown here, the loss of osseo-integration along the vertical implant axis has

led to a long cantilever and to a situation where the implant`s abutment shows a high mobility. In the case of PEEK-compound implants under observation here (Perso C, Perso B), the low „Modulus of Elasticity“ is combined with an unsuitable design of the implants, and this must lead to frequent problems in the clinical reality. PEEK materials with higher Modulus of Elasticity , e.g. “Motis” (a PEEK compound with carbon fiber enforcement) could work better, because it reaches values of up to 12 GPa, which is in fact really close to the bone. Unfortunately this material is black, and the water uptake of all compounds of PEEK is considerably high.

PEEK has stable crystalline form but when blended with composites like carbon fibres by injection moulded technique, there are changes of nucleation in polymers and a change in original crystallinity. Furthermore it becomes impossible to predict the mechanical behaviour of the device and the load transmission properties, if randomly parts of the implants are cut off and the long chains of molecules are altered and shortened.

Note that the “osteolytic” situation seen in both patients in the upper jaw around the PEEK-compound implants could also be interpreted as a reduction of mineralization of the bone, and this could be the bone`s answer to the (from bone`s point of view) hyper-elastic implant material. This process could add up with localised overload due to the very sharp implant`s edges, and result in the massive loss of bone which we have observed.

Note also, that if these lateral basal PEEK-compound implants would be implanted deep

into the basal bone and heal unloaded or rigidly splinted, a regular integration could occur. This integration resembles an extra-territorialisation (Donath) and it includes a regular corticalisation of bone in the close vicinity of the implant. Presumably for this type of reaction large amounts of vertical, protective bone are required to protect the implant from any adverse loads which could deform the implants. This way the hyper-elastic properties of the material would be undetectable for the bone and strict rest for the implant could be guaranteed for about four months at least. Cortical contact would be mandatory for this procedure, because the BIC of PEEK and PEEK compound is known to be low: nevertheless cortical wounds would heal and integrate the implant as long as the material itself is passive enough and does not trigger either encapsulation or toxic reaction. PEEK seems to be such a material.

Claim 2: “No artefacts in radiographic imaging”.

This claim is also misleading, as modern CT-machines provide good pictures without artefacts even around multiple implant cases. The downside of PEEK also PEEK-compounds with BaSO₄ is the low radiographic visibility and the low optical visibility of the material in the bleeding environment of the operation site. This makes it extremely difficult to remove especially partially integrated and highly mobile implants which hold in macro-retention.

Claim 3: “No heating in MR-imaging and X-ray-therapy.” And “there is no need to remove the implant for type”.

Also this claim is misleading, as heating around dental implants in MR-imaging was never described, and there is no such thing as “X-ray-Therapy”. In case that the author of the prospectus wanted to express that modified PEEK/implants are safe to use in case of a combined chemotherapy with ray-therapy, he is presumably also wrong, because at least in the two cases observed here, massive infection and osteolysis was seen even without such therapy. Who would remove a metallic dental implant for a CT-scan?

Claim 4: “Metal free, no corrosion”

The authors do not see any advantage in metal free implants or constructions and the claim that there is “no corrosion” is therefore also misleading. In the oral cavity corrosion or currents between different metals play a minor role, because the saliva constantly tends to extinguish electrical potentials. For the durability of treatments and especially cementations and for protection against (secondary) caries, the real problem is gap-corrosion which can occur between all kinds of materials. e.g. between (all type of) abutment heads, also at natural abutments, and the prosthetic constructions. This gap corrosion affects also non-metallic molecules and it can only be overcome by precise prosthetic work-pieces and precise cementations.

The claim of a “metal free”-therapy is anyway absurd, if bridges from zirconium are then incorporated on PEEK implants. Zirconium is a metal.

Titanium and titanium are constantly covered by a stable layer of oxygenized titanium and this

layer prevents any other corrosion as it can be seen e.g. on corrosive metals such as iron.

Claim 5: “Post extraction insertion in all sectors”. We consider also this claim misleading, because from our observations we had to come to the conclusion, that immediate loading around the implants under discussion here is not a good option, especially in low bone cases.

Claim 6: “Due to the equivalent flexibility of jaw bone the implants PEEK Perso C®, and Perso B® will stimulate the remodeling of bone (Osteo-conduction).”

This claim lacks not only of any proof, it is simply wrong:

- PEEK does not stimulate the remodeling of bone,
- such a remodeling is the last thing we would want in dental implantology. Implants, - especially if used in immediate loading - require highly corticalized bone around them and mechanical stability as well as the lowest possible metabolic activity, and possibly without and osteonal remodeling.
- Osteo-conduction is not found in PEEK at all. It is known, that PEEK shows a low bone-to-implant contact (BIC) and it integrates mainly in the corticals due to the high tendency of all corticals to close (repair) after injuries.

Claim 7: “Adjusting the implant to the patient and not vice versa”.

This claim seems to aim at the “iso-elastic properties” of the implant material. As pointed out under claim 1, iso-elasticity is neither an advantage nor a prerequisite for osseo-integra-

tion. In fact over the last 30 years it has been proven that implants of all kinds, made from Titanium and Titanium alloy, integrate predictably.

4.3. Radiographic evaluation

Implants from pure PEEK are not visible in x-ray at all (Figs. 12, 13). Implants from modified PEEK-compound, containing BaSO₄ as x-ray-marker are visible to some minor extent in radiographs. At least this allows one to evaluate their integration and to localize the implants.

As implant failures are mostly multi-causal we must consider other reasons for the failure also. Possible reasons are wrong prosthetic equipment of the implants (i.e. either wrong prosthetic strategy or mistakes in the design of the prosthetics). Furthermore failure of cementation may be contributing. In the two cases some of the implants did not show any connection to the bridgework, and nevertheless the lateral-basal implants did not integrate at all. This may indicate, that lateral-basal implants made from PEEK-compound show a low integration potential at least in the resorbed distal maxilla.

4.4. Comments on the design of axial Perso-C®- implants.

Perso C® implants may work well under optimum conditions, when no vertical bone loss takes place along the axis of the implant. As soon as the bone recesses however, the remaining parts of the implant (i.e. the parts anchored deep in the bone) are too thin to withstand the masticatory forces and the implant body deforms. Namely lateral forces will then bend

the implant to both sides, lingual and lateral, which leads to even more bone loss, until finally only the apex of the implant remains integrated in the 2nd cortical. The design of Perso C® implants do not take into consideration the possibility of vertical bone loss, they are designed for the ideal case only. In fact the more bone is lost, the more deformable the implant gets, Hence higher localised stresses in the descending neck area will occur and more bone will be lost. As soon as vertical bone gets lost, these implants are not iso-elastic any more, they are wobbly.

4.5. Alternative treatment possibilities and outcome evaluation

As an alternative to our treatment it would also have been possible to first extract the implants and then (in a second intervention) to carry out a conventional sinuslift or bone block augmentation, followed by 2-stage-implant placement. The patients did not desire these lengthy treatment protocols. Due to the large perforations of the basal sinus corticals a conventional sinuslift would have been more risky than in "normal" cases, where the lower cortical of the sinus is still present and a minimal residual height of the alveolar crest supports new bone formation and the maturation of the graft. Therefore probably a bone block transplant would have been the method of first choice to reconstruct the inferior sinus wall.

We would like to point out that right now we cannot report about the long term outcome of our treatment.

4.6. Bridge material considerations

From a mechanical point of view it makes no sense to combine elastic (deformable) implant designs with a super-stiff bridge material as done here: Zirconium shows virtually no elasticity at all. In combination with non-resistant (i.e. "iso-elastic to bone") implant material and deformable implant designs this leads to a situation where localised loads will be hitting only one implant (the one nearest to the load) and they will deform it, thereby overloading the bone. Sarot et al (8) reported as a result of their FEM-calculation similarly: in CRF-PEEK implants, compared to titanium implants, the stresses are 30 % higher in the neck area and the adjacent bone.

This event is especially likely in immediate load procedures when the bone near the load transmission surfaces is under strong post-operative remodeling while being loaded from mastication.

Deformable implants never give the desired result of better load distribution or adaptation (9). Higher loads always require larger load transmission surfaces or bone of larger resistance, i.e. higher local mineralization or cortical/corticalized bone.

4.7. Consideration on the possibility of cementation

If, as pointed out under 4.6, single implants deform, other abutment of the bridges may not deform. This leads to a situation where single abutments come under tensile forces, and on these abutments the cementation will then fail. PEEK and PEEK-compound abutments show no roughness, because they are created in an

injection moulding process. Roughening them up in the oral cavity is dangerous and gives an unpredictable mechanical result, because mechanical destruction of the molecules, which were well aligned during the production of the implants, leads to follow-up destruction of the molecules integrity and adhesion. Hence cementations on the destroyed surfaces will be likely to fail, and exactly this was observed in the two patient cases.

5. Conclusion

In this article two cases are discussed, which had been treated with crestal and lateral-basal PEEK-compound-implants. Both patients received their implants in the same clinic in Western-Europe. This is not a case series, nor a cohort study, we are reporting on two similar clinical cases treated under the same conditions and with identical medical devices.

As our analysis shows, probably many of the claims of the manufacturer are not true, and in the clinical reality we found many flaws in the devices.

Our analysis also shows, that probably several of the features of these implants (such as: thin and overly elastic design of both vertical and lateral-basal designs, large mucosal penetration diameter, low contact area of the crestal types to bone, small holes in the base-plates with subsequent blockage of blood supply and bony pervasion, missing possibility to adjust the implant`s bone transmitting surface with at least some precision) will, - especially under immediate load conditions-, lead to typical failure patterns, especially in low bone cases and in immediate loading.

Low visibility on X-ray and during the

operation makes it difficult to remove partially integrated (actually: mechanically locked-in parts of) crestal types of the implants under investigation here. Besides the extremely low costs of production (less than 1 Eur per piece), the design of Perso C[®] and Perso B[®] do not provide any advantages and there are a number of massive risks for the patients associated to these implants.

We would like to point out again that PEEK-Compounds (e.g. those showing higher Modulus of Elasticity) as such may be well suited for use in traumatology and even dental implantology, if proper implant designs and adequate treatment protocols are chosen.

The question, whether or not it makes sense to search for a replacement of well suited and force resistant titanium and titanium alloy in dental implantology, must be raised at this point. Allergies to titanium as implant materials are extremely rare and mainly used as an excuse to unknowledgeable patients after failing dental implant treatments.

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