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CLINICAL SUITABILITY OF DIFFERENT IMPLANT DESIGNS: ANALYSIS OF CUSTOMER COMPLAINTS REACHING THE IMPLANT MANUFACTURER.

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Contact

publishing@implantfoundation.org

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**Clinical suitability of different implant designs:
Analysis of customer complaints reaching the
implant manufacturer.**

Author and Corresponding author:

Prof. Dr. Stefan K.A. Ihde
Head of Dental Implant Faculty
International Implant Foundation
Leopoldstr. 116
DE-80802 Munich/Germany
email: ihde@ihde.com

Abstract

Customer complaints regarding dental implants stemming from dentists and surgeons world-wide were reanalyzed for a defined period by an implant manufacturer. The number of “complaints related to implants” vs. “implants sold” reveal that implant with polished endosseous surface and designed for immediate loading protocols as well as single piece implants are significantly less prone to customer complaints compared to traditional 2-stage systems ($p < .001$) with rough (sand-blasted/acid etched) surface ($p < .001$) and larger endosseous diameter. As we had planned to publish the data and collected them meticulously, this study is prospective.

Keywords: Implant complaints, implant surface, implant design, immediate loading

1. Introduction

In literature survival rates of implants are typically determined in studies undertaken in universities. Such studies may have a doubtful base, because inclusion and exclusion criteria at universities are different compared to offices of private practitioners. Another problem is that comparative studies between two systems or even two technologies are not available. The reason is, that usually specialists for alternative treatment strategies are not available in one center. Bad outcome of real comparative studies could affect the relationship between the university and de-rail the vital financial support of an implant manufacturer.

Another problem is the definition of success criteria in clinical studies. In a number of studies we find only such implant counted as lost, which had reached the phase of the prosthetic treatment. Other authors include all implants consecutively placed. Data considering the intend-to-treat-principle are to our knowledge not available in dental implantology. Hence studies are done with a small number of patients and usually only a few dozens of dental implants.

In our study we have chosen a different approach to assess the influence of the design and the surface on the outcome of a dental implant treatment. Based on the world-wide sales of 254.113 consecutive implants of all types manufactured by Dr. Ihde Dental AG (www.implant.com) we have related the number of sold implants to the number of complaints which were made to the quality department of the manufacturer.

2. Material and Methods

The manufacturer produces a broad variety of implant designs. All precision part manufacturing and packaging as well as cleaning and sterilization for all systems takes place in the same facility, using the same raw materials, machines, chemicals, cleaners, workers, and the same production protocol. All products are CE-marked and produced in a facility working under ISO 13495 (formerly ISO 9001, ISO 46001) regulations. The implants are registered outside of the EU in many countries around the world. Returned implants from all countries entered into the calculation.

We have compiled data from the sales department and the quality department (working on returned items).

The following implant systems were controlled for implant returns, and the following groups were made.

Group 1: Single-piece implants (rough and polished surfaces)

- Compression screws (KOS group of implants)
- Crestal basal implants (Strategic Implant®, BCS, GBC, Beces)
- Lateral basal implants (BOI/TOI)

Group 2: Two-Stage (2-piece) implants (rough and polished surfaces)

- Standard cylindrical full screw implants (neck max. 4.8 mm d, brands SSO, STI; Straumann-clones)
- Wide neck cylindrical full screw implants (STW, GTW; Straumann-clones)
- Bone Level Plus Implant (compatible to Straumann Bone Level)

- Internal Hex standard implant (Hexacone/GIH)
- Tri-Lobe Implants (Place)
- Tuber-Pterygoid screws (TPG)

Group 3: Implants with fully polished surface for immediate loading

- Strategic Implant® (BCS/GBC/BECES)
- Lateral basal implants (TOI/BOI/COI)
- Tuber-Pterygoid screws (TPG)

Group 4: Implants with sandblasted/etched

- Standard cylindrical full screw implants (neck max. 4.8 mm d, brands SSO, STI; Straumann-clones)
- Wide neck cylindrical full screw implants (STW, GTW; Straumann-clones with wide neck)
- Bone Level Plus Implants
- Internal Hex standard implant (Hexacone/GIH)
- Tri-Lobe Implants (Place)
- Compression screws (KOS group of implants)


Complaint rates (p_c) between different groups were analyzed using cross-tables and χ^2 tests as well as odds ratios with respective estimates of confidence intervals (in the case of 2x2 tables). Also, confidence intervals of category complaint rates were computed.




Because economical interest of the manufacturer had to be protected, the study period (showing in which period the implants have been sold) as well as details about sales of each system cannot be revealed in this publication in all details.

Implants with identical outer design but with different internal connection (e.g. Full screws with internal conus and Full screw implants with internal octagon) are in the same group.

3. Results

Results are based on N = 254.141 sold implants of all systems are shown in Table 1. n = 178.201 implants belonged to group 3 (immediate load systems), the rest belonged to the 2-stage group of implants. The overall return rate of implants is 0.282%. Figure 1 illustrates estimated complain rates and their confidence intervals in relation to the total return rate.

Category	Implant design	Returned implants % (UCI; LCI)	Implant design and typical modus of usage	Clinical appearance (average size and length)	Endosseous surface
1	Compression Screws Implants (KOS/GCS - Group)	0.13 (0.109; 0.155)	Single piece, Immediate loading		Sandblasted

2	StrategicImplant® (BCS,GBC,Beces)	0.03 (0.022; 0.050)	Single piece, Immediate loading		Polished/ machined
3	Internal Hex Internal Cone StandardImplant: Hexacone®	0.52 (0.455; 0.601)	2-piece,2-stage Healing phase		Sandblasted/ etched
4	Standard Cylind- rical Full screw ImplantSSO®,STI® (Strauman-clones)	1.06 (0.907; 1.237)	2-piece,2-stage Healing Phase		Sandblasted/ etched

5	Wide Neck cylindrical full screw implants STW, GIW	2.77 (1.946; 3.917)	2-piece, 2-stage Healing phase		Sandblasted/ etched
6	Internal Hex/ internal Telescope Implants Xign® (Xive compatible)	0.54 (0.407; 0.701)	2-piece, 2-stage Healing phase		Sandblasted/ etched
7	Lateral basal Implants (Disk- type-implants) BOI® / TOI®	0.10 (0.033; 0.282)	Single piece, Immediate loading		Polished/ machined
8	Tubero-Pterygoid- Screw implant TPG	0	2-piece, immediate loading		Polished/ machined



9	Bone Level Plus Conical Screw Implant (Straumann-clone)	1.42 (1.090; 1.838)	2-piece, 2-stage Healing Phase		Sandblasted/ etched
10	2-stage compression screws STO, STC, (Straumann-clone)	0.91 (0.650; 1.277)	2-piece, 2-stage Healing phase		Sandblasted/ etched
11	Place® (GPL)	0.60 (0.223; 1.491)	2-piece, 2-stage		Sandblasted/ etched

Table 1: Calculation of returned implants vs. sold implants in the different groups of designs.

Polished two-piece implants for the tubero-ptyergoid region showed no complaint at all in the observation period. However, only 350 sold pieces are included in the comparison.

Rough implants with large neck diameter (4.8 mm and larger) show the highest complaint rate (2.77%). The complaint rate for single piece basal screw implants (Category 2, Systems: BCS, BECES, GBC) is approx. 23.3 times lower than for all other 2-piece implants.

Prior to group analyses, categories 4+5 and 3+6+11 were tested for significant within-group differences. Thereby, comparison of groups 4 and 5 yielded significant differences in complaint rates, $\chi^2(1) = 26.349$, $p < .001$ whereas results of 3, 6 and 11 indicated no significant effects, $\chi^2(2) = 0.119$, n.s..

Comparing category 4+5 ($p_c = 1.182\%$) against 10 ($p_c = 0.913\%$) yielded no significant difference in complaint rates, $\chi^2(1) = 1.818$, n.s., $OR = 1.297$ (0.907; 1.853). However, when comparing implants in categories 4+5 (Straumann-clones with cylindrical core and minimal threads, in different implant diameters) against implants in categories 3+6+11 (2-stage-implants with conical core and more aggressive threads) ($p_c = 0.527\%$), results indicate a significant difference in return rates, $\chi^2(1) = 77.097$, $p < .001$. The odds of observing a complaint in group 4+5 are $OR = 2.257$ (1.875; 2.717) times higher than in group 3+6+11.

When comparing category 4 (standard Straumann-clone with cylindrical core and max. platform diameter of 4.8 mm) ($p_c = 1.059\%$) against

9 (Straumann-compatible implant with conical compression screw threads) ($p_c = 1.418\%$), no significant difference emerges, $\chi^2(1) = 3.440$, n.s., $OR = 0.745$ (0.552; 1.005).

Complaint rates of categories 3+6+11 (2-stage-implants with conical core and more aggressive threads) are significantly different compared to category 9 (Bone Level Plus), $\chi^2(1) = 49.975$, $p < .001$. Complaints in group 3+6+11 are $OR = 0.368$ (0.277; 0.490) times less likely to be observed than in category 9.

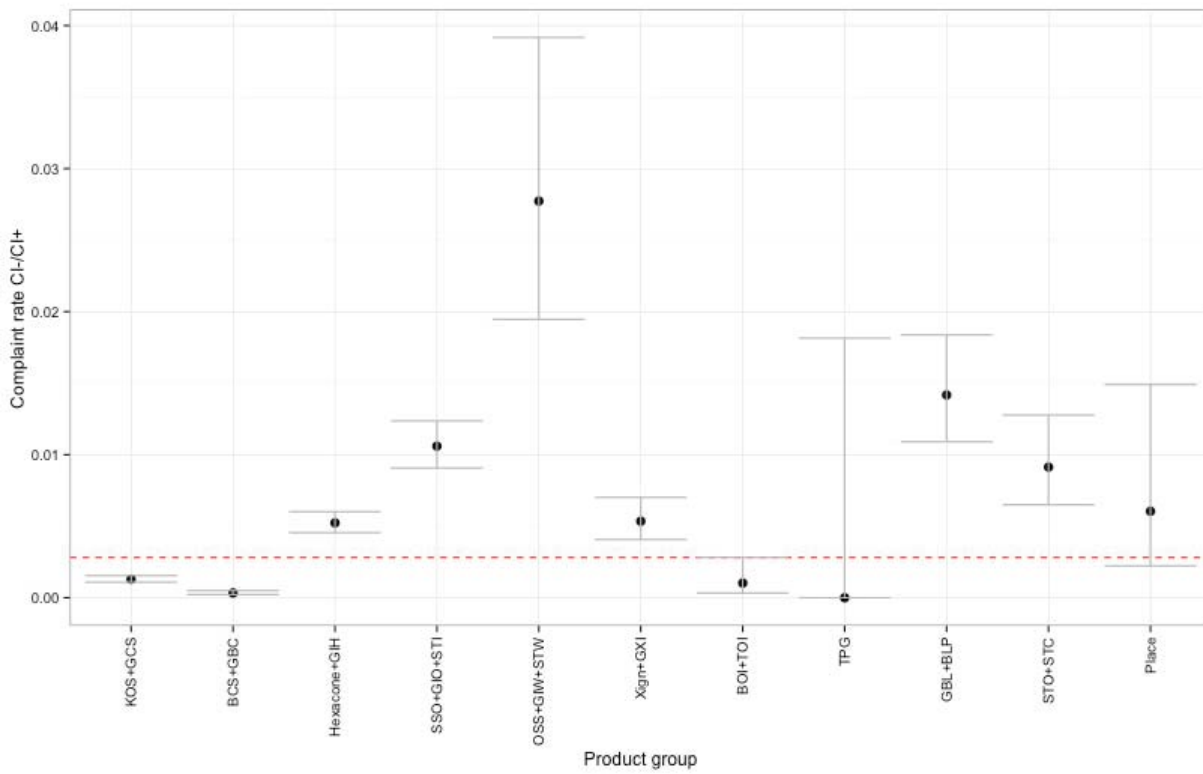


Figure 1: Product complaint rates of categories (dots) together with 95% confidence intervals and total return rate (dashed line).

Grouping the systems as described in the material and method section of this publication was then done (Table 2).

Group	Surface & Design of implants	Returned implants %
Group 1	Single Piece Implants (rough and polished)	0.09
Group 1 plus System TPG	Immediate Loading Systems (1-piece & 2-piece)	0.09
Group 2	All 2-stage Implants with sandblasted/etched surface	0.73
Out of Group 2	Conical core, medium retention thread sandblasted/etched surface (Hexacone, Place, Xign)	0.91
Group 2 plus TGP	All Implants with Polished Endosseous Surface (single piece, 2-piece)	0.70
Group 3	All Implants with Polished Endosseous Surface (single piece, 2-piece)	0.04
Group	All Implants with sandblasted/etched Surface (single piece, 2-piece)	0.39

Table 2: Grouping of different implant designs according to the mode of application (Immediate Loading, 2-stage) and according to surface characteristics (rough vs. polished surface).

Comparison of polished ($p_c = 0.037\%$) and rough ($p_c = 0.393\%$) surfaces yields a significant difference in complaint rates, $\chi^2(1) = 245.130$, $p < .001$. Thereby, the odds of observing complaints in the group of rough implants is $OR = 10.777$ (7.429; 15.630) times higher than for polished implants.

With regard to implant design, 2-piece implants ($p_c = 0.741\%$) shows significantly higher complaint rates than single piece implants ($p_c = 0.089\%$), $\chi^2(1) = 795.968$, $p < .001$. The odds for implant complaints are $OR = 8.408$ (7.044; 10.040) higher for 2-piece implants, compared to single piece implants.

The implant's score also shows significant impact on complaint rates, $\chi^2(1) = 291.216$, $p < .001$. Thereby, conical implants ($p_c = 0.309\%$) exhibit $OR = 3.856$ (3.266; 4.553) times lower odds of being returned, compared to cylindrical implants (1.182%).

Thread types also indicate, to be significantly related to the outcome, $\chi^2(3) = 982.317$, $p < .001$. Aggressive threaded implants for 2nd-cortical engagement show the lowest rates of complaint ($p_c = 0.033\%$), followed by compression screws ($p_c = 0.159\%$), cutting ($p_c = 0.527\%$) and cylindrical implants with minimal threads ($p_c = 1.229\%$).

When comparing group 3 and 4 against each other it must be noticed that in Group 3 mainly single piece implants are found (99.7%), whereas the percentage of single-piece implants in Group 4 is only 57.1%.

4. Discussion

Dr. Ihde Dental AG is encouraging all customers to return failed or un-usable implants by replacing those implants and other parts free of charge. There is no post-sales time-limit for this warranty, i.e. such replacements will be done even after many years. We therefore assume that most customers will actually send back failed implants if failure happens. Returned implants reach the manufacturer either directly or through the national or local dealer. Implants which were however removed in a different office will probably not be returned to the manufacturer.

Exclusion criteria

We have excluded from this study returned implants, which are related to problems with the insertion tool (e.g. defective insertion tools damaging implant connections).

We did not exclude implants which had never been placed, because they have for example fallen on the floor after opening the pack, as this is a typical design-related problem and we cannot be sure regarding the reason for the return. Such returns were neglectable however in relationship to implants which have been lost after placement. All brands manufactured by Dr. Ihde Dental AG (Dr. Ihde Dental-Brand, Oneway Biomed-Brand, Simpladent-Brand) were included and not calculated separately.

In the manufacturer's "instruction for use" no restrictions are made regarding the use in upper or lower jaw. So we can assume that all implants were used in both jaws, and that the treatment provider was well able to search for

the best fitting implant for the given case. The only strict recommendation given therein is to load (splint) immediate loading systems within 72 hrs (3 days). In the world-wide training course the manufacturer encourages the treatment provider to use the Strategic Implant® (Category 2) even in cases of severe periodontal involvement, right after extractions, and even in severely infected sites under local disinfection coverage. Hence we have to assume that the implants are used also in real life under those conditions. Such conditions are not at all suitable for rough 2-stage implants, who are delivered with instructions which list up a large number of contra-indications and other limitations for use as known in 2-stage implantology. For 2-stage systems (except for TGP) standard healing times are described to be 3 months in the lower jaw, and 5-6 months in the upper jaw.

The manufacturer also does not limit the use of a Strategic Implant® to sites which are free of periodontal involvement, because one study had shown, that lateral basal implants even perform better if such involvement is given and if implants are placed right after extractions¹.

What are the strengths of this study:

1. The sample size is extremely big.
2. The information stems from practitioners and not from universities (not one single university was included)

3. The practitioners were choosing out of 10 systems the ideal system for them and the case, which they assume would work best in their hands. This allows a good comparison of systems.

Where could weaknesses to our approach be hidden:

1. We cannot be sure that really all lost implants are returned. Especially years after the treatment the practitioner may have changed the supplier or the local dealer may have dis-encouraged the doctor to return the implant.
2. Implants which have been taken out in a different office will probably not be returned to the original manufacturer.
3. The reason for the very good result for polished implants may partly be lying in the fact that practitioners may clean them (like instruments) and re-sterilize and re-use them, just as it is done in many countries with machined or polished fracture-plates in traumatology. Such implants will not be sent back to the manufacturer, as they can be re-used (although such re-use is not advocated in the instructions for use).
4. Statistical comparisons of complain rates are bivariate. Confounding effects of external factors and / or interactions between implant factors might have occurred.

¹Kopp S., Kopp W. Comparison of immediate vs. delayed basal implants; J Maxillofac. Oral Surg, 2008(7)1:116-122

This is not a study about implant success rates, it simply describes and compares the number of complaints from dental clinics and relates it to the sales-figures.

Many of the implants were sent back including cemented (and sometimes screwed on) prosthetic work-pieces. This shows that our sample includes not only early losses of unloaded implants, but also losses, which occurred during the usage phase of the implants.

Only some implantologists reported about the period of usage of the implants in the mouth. We did not see a way, how to use this information in this study, because too often full information was missing.

Ancient dental literature states that polished implants in general are not suitable for immediate loading. This statement may be true for implants placed into spongy bone areas, it is, - as this study and decades of experience in traumatology and orthopaedic surgery shows, definitely not true for cortically anchored implants. We found hence also successful reports on early or immediate loading of polished implants².

Astonishingly the "Straumann-compatibles" showed a high complaint rate. The design of these implants feature almost no macro-retention and the cylindrical endosseous design does not allow to compress spongy bone while inserting the implant.

The success rate of these devices depends strongly on the endosseous design. Implants with almost no thread-retention (Category 4, threads 0.15 mm thicker than the core) perform worse than implants with the same connection, but with conical design and larger compression-threads (Category 10, threads 0.25 mm thicker than the core).

Rough-surfaced single-piece compression screws (Category 1) perform however much better than 2-stage systems with the same surface (Category 10).

The present study also shows, that with the help of excellent marketing even quite unsuitable implant designs (Categories 4, 5, 9) can become world market leader. It seems that the real features of an implant design is not correctly estimated by many implantologists, they just follow the main stream.

Direct comparison between this study and other studies following a defined cohort of implants are probably possible. We found that the rates of non-complications can fit to literature data regarding immediate or early loading³.

Finally our study shows, that there is not a "good" or "bad" manufacturer for dental implants, the complaint-rate (and thereby also the "success"-rate) is very closely connected to the implant design.

²De Bruyn H., Collaert B.: Early Loading of Machined-Surface Branemark Implants in Completely Edentulous Mandibles: Healed Bone versus Fresh Extraction Sites *Clinical Implant Dentistry and Related Research* 10/2002; 4(3): 136-142.

³Nikolai J., Zarb G.A. Immediate and early implant loading protocols: A literature review of clinical studies. *The Journal of Prosthetic Dentistry*, 94, (3) 2005, pp 242-258

5. Conclusion

Within the limits of the design of this study it can be concluded that:

1. Implants with polished endosseous surface and cortical engagement lead to the low-estrated customer complaints: only 0.04% of such implants are returned.
2. Single piece implants designed for immediate loading yield much lower complain rates compared to "2-stage systems", especially if the 2-stage-systems provide a rough endosseous surface for "biologic osseointegration".
3. Implants with conical core exhibit a 3.8 times lower complain rate compared to cylindrical core implants with minimal threads.
4. Aggressive threaded implants for engagement in the 2nd cortical show the lowest rate of complaints (0.03%), compared to other thread types, and compared to all other implants.

Based on the results of this research, we give the recommendation to our customers to use polished, single piece implants for anchorage in the 2nd cortical in an immediate load protocol in order to profit from the lowest possible rate of complaints. The use of polished implant devices in an environment with strong bacterial load (such as the oral cavity) is also from a logical point of view the only safe option.

It is completely useless to buy and use implants with a "specific surface", as these surfaces will increase the probability of complaints.

Besides these rough surfaces (sand-blasted, acid-etched, etc.) trigger "peri-implantitis", especially if combined with large implant diameter.

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