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Characterizing and Controlling the Risk Factors in Manufacturing Dental Implants

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Abstract

Background

Subtractive manufacturing have been popular in dental implant production. In order to increase the survival rate of the dental implants, a comprehensive risk analysis has been performed in the technical documentation of the products.

Purpose

In this paper the most common risk factors categorized as implant-related, surgeon-related, patient-related, and maintenance-related risks in the manufacturing process, application, the long term usage and the so-called survival rate of dental implants are studied.

Methods

The importance of any of the potential risk factors which is directly or indirectly related to the product quality is assessed. In the evaluation stage, the factors are sorted based on their severity and probability of occurrence, brought to the risk criterion table. Proper measurement called as mitigations were used to standardize the risks to the acceptable criteria. The standardization could be through reducing the severity of the risk or through reducing the probability of its occurrence, or even both of them. Advancing from the hazardous situations was an expected aim for any of the risk factors.

Results

The equivalent risk assessment factors are compared in pre-mitigation and post-mitigation stages. The main aim was to see whether the risk level of the factors reduces to the acceptable or conditionally acceptable region. Falling in to the conditionally acceptable region makes the application of the product to be under sufficient warnings, which orders to take enough pre-cautions for the user or operator. For most of the risk factors, there was a concern that the measurements are able to only improve them in the frequency of occurrence, however, the results show that there are solutions to improve the severity as well.

Conclusion

Through this comprehensive study, the risk analysis file is completed however it can be even more complete, in the future, at this industry. In the further studies, discretizing the steps of severity or probability to finer steps, and ultimately converting them to a continuous form would be aimed.

Key words: Dental implant; ISO 14971; Harm reduction; Hazard, Risk management.

Introduction

Even if there are comprehensive studies on the causes of the dental implant failure, there is still a considerable rate of failure [1-2]. Investigating in the contribution of the risk analysis in completing the technical documentation of the dental implant through the manufacturing process is still necessary. There are different factors that are threats for the health of patients when placing dental implants as a root treatment solution. In general, usage of a dental implant is just rational if the benefits overcome the consequences of risk factors. Ultimately, risk analysis helps to provide marketing surveillance. However it has been used a lot for the clinical trials as well [3-4].

Some researchers believe that there are only two main categories of patient-related and implant-related risk factors, which are generally accepted to contribute in the success rate of surgeries [1-2, 5]. However, some researchers considered one more aspect of surgeon-related factors which itself is categorized under the implant-related factors [2]. This is partly because some of the angulated abutments are machined by the surgeons or relevant laboratories from the pre-milled abutments. There is another aspect to this problem which is related to the maintenance phase. In the next section, these aspects of the study have been elaborated as the general causes of the failure, where all the factors from the implant design and manufacturing process, to properly placement, and from the post-surgery to long-term survival are covered [6].

Implant-related risks: Implant-related risks mainly originate from the implant design parameters such as dimensions, aspect-ratio (length/diameter), material properties, safety factor and material roughness [6]. In addition, the manufacturing process, packing, storage, and providing adequate information to prevent misuse are also important stages before the surgical process. Surgeon-related risks: Parameters such as surgeon's measurement from the bone level thickness, soft tissue level thickness, and timing of the surgery stay under the surgeon-related risk factors. Some of the surgeon-related factors are dependent to surgeon decisions and observations such as being adjacent to other teeth or implants [6-9].

Patient-related risks: The third category is the patient-related risk factors, which is focused by some other researchers [8-10]. Patient-related risk factors cover a wide range of diseases' history in patient. In addition, the current condition of skin, soft tissue and bone, as well as bleeding, smoking, alcohol consumption, the presence of bacterial plaques, and soft tissue volume growth rate are constructive factors in the survival or the failure of dental implants [10-11].Maintenance-related risks: The next category of the risks called as maintenance-related factors which are mainly focusing on the post-surgery care and maintenance issues. This category is mainly efficient with the corporation of the patients. Proper instruction and the role of patient are critical for achieving higher survival rate from this stage. In this work, although the patient-related factors are more focused by the authors, there is almost no maintenance responsibility lying on the patient yet.

In this research the main aim is to fully study the risk factors related directly to the product quality or indirectly through the processes of manufacturing and using dental implants. In order to formulate the importance of each risk factor, and provide the best surgery strategy, every patient's technical file needs to be documented based on a comprehensive risk analysis [10]. Thus, the risk analysis from the peri-implant stage has been documented. A parameter called in the literature as Equivalent Risk Assessed (ERA) [3] or in this work as risk priority number (RPN) collected and calculated from the severity and probability of the risk factors and have been used largely in this research. And the importance of the risk analysis in technical documentation of the dental implants is highlighted. Finally, the risk factors are characterized, analyzed, and control of the hazardous situations studied in dental implant production.

Materials and Methods

Based on the available standards for the risk classification of the medical devices, any risk at the application of the medical devices would be acceptable, conditionally acceptable or unacceptable. As defined in Figure 1, there are 5 levels of severity including negligible, minor, serious, critical, and catastrophic which are rated from 1 to 5 based on their intensity [3]. In addition, the probability of occurrence of a hazardous situation has been classified. It is basically a continuous parameter, but in this case has dissected into 5 different levels including frequent, probable, occasional, remote, and improbable rated downward from 5 to 1. The RPN factor is then calculated from the product of severity and probability as the accumulated risk factor.

Figure 1: the acceptance criteria for the accumulated risk factor priority number. Three colors of green, yellow and red are symbols for the acceptance, conditionally acceptance and unacceptance of any specific risk for the product

After estimating the accumulated risk factors, risk versus benefit analysis is necessary. While dental implants restore the function of tooth's root or in some cases restore its anatomy [1], the benefits should outweigh the risks. In Table 1, the green blocks represent the risks areas with acceptable benefits. The yellow blocks represent the conditional acceptance of the product, where there should be adequate warnings supplied for the users from the manufacturer. The specific terms of use have to be clearly emphasized in the instructions for use to prevent foreseeable misuse. In order to start the analysis, at the evaluation stage, all the risk factors with their foreseeable sequence of events and their severity level from the design stage to the long term application are assessed and listed. Through the assessment, the hazardous situations are evaluated and the harms are predicted.

After that the primary (proposed) solution to alleviate the concern (altering the risk) is provided. Thus, solutions for reducing the probability of occurrence or lowering the level of severity are investigated. In the results sections, the RPN is recalculated based on the new conditions, and the residual risks are measured to see whether they are acceptable or not. All the process of risk assessment of dental implants is graphically shown in Figure 2.

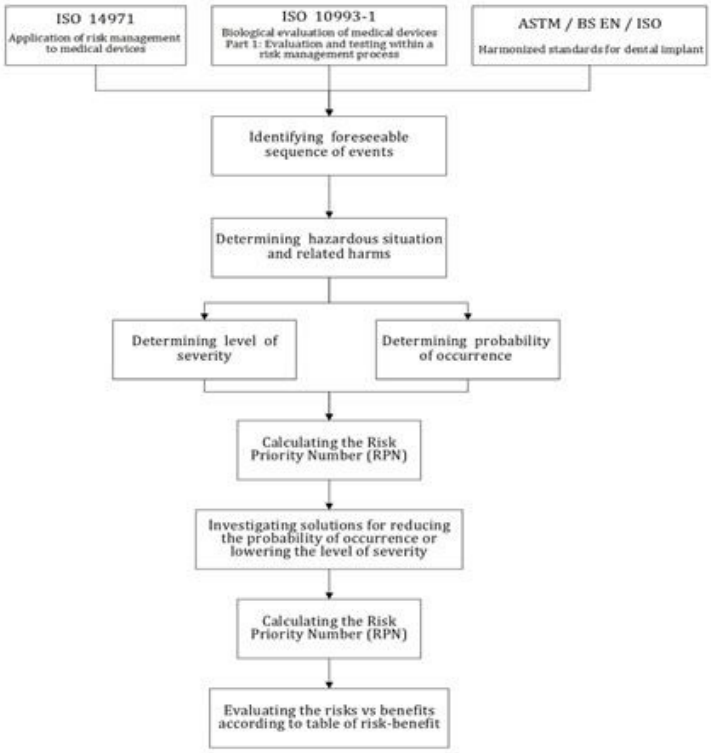

Figure 2: General structure of the risk management activity

There are several types of mitigations that have been proposed for currently considered risk factors. These mitigations are categorized based on their applications and the place they come to affect in the manufacturing process line:

- Misuse preventive design,
- Process control,
- Three steps of quality control including initial (raw material) QC, in-line (semi-finished product) QC, and final product QC,
- Information transfer assurance.

The mentioned items are the main topics for mitigations, and as you have seen in the above sections, the sub-categories are used in each case. In this research, risk analysis of the medical device has been studied according to the ISO 14971 medical device regulations. The international standard offers a variety of methods to find risks and analyze the risk factors. One of the most common methods is hazardous analysis and critical control points (HACCP). A simple method of evaluating risk factors based on their RPN number was used here. Then, three risk types are considered, however, the criteria were tighter than the sample provided in the standard.

Results

In this study the authors are motivated to assess the risk of the failure at the dental implants for the marketing purpose. To complete the risk analysis mitigations have been implemented to reduce the probability or severity of different risk types. Different types of risks of the failure of the products, and also the procedures are investigated. In this section, the list of the detected risks has been provided within the Table 1.

Table 1: List of the risk factors of the dental implant production

No	Foreseeable Sequence of Events	Hazardous Situation	Harms	Severity	Probability
1	Out of tolerance circularity, cylindricity and straightness of the titanium bars	Crashes on the external area of machined products	Lower primary stability	Minor	Occasional
2	Out of tolerance circularity, cylindricity and straightness of the titanium bars	Failure in connection zone of machined product	Loss of prosthetic component (detachment)	Minor	Occasional
3	Low quality titanium bars based on composition criteria	Low quality of machined product surface	Lower primary stability	Minor	Remote
4	Inappropriate room temperature of the CNC unit	Lubricant oil properties differ and tools might be overheated	Reduced CNC tools life and lower machine quality	Serious	Occasional
5	Oil contamination from CNC	Inappropriate sandblasted surface property	Slowed osseointegration	Serious	Improbable

6	Residual internal filings from CNC	Low fitting of abutment	Loss of prosthetic component (detachment)	Minor	Remote
7	Inappropriate room temperature in QC lab	Calibration of the visual measuring device is lost; lower accuracy of the measurements	Dimensional QC data is not accurate	Serious	Remote
8	Operating the sandblasting device with different setting from designed instruction	Inadequate sand level, low pressure of nuzzles, improper nozzles' angles	Low surface roughness and reduced osseointegration	Serious	Remote
9	Residual sands between threads from sandblasting	Non biocompatible implant	Untreatable local infection and explantation	Catastrophic	Probable
10	Variation in the process of anodising and colouring the abutments	Non biocompatible prosthetic parts	Irritation/ Inflammation in local (Self Limited)	Minor	Remote
11	Residual micro-particles on final product	Infection	Local Infection Recoverable	Critical	Remote
12	Air particle amount in clean room is beyond the standard level	Particles in the pack of final product is above the prescribed range which might lower the quality of sterilization process	Local Infection Recoverable	Critical	Remote
13	Product is not completely sterilized	Using unsterile implants leads to local infection	Untreatable local infection and explantation	Catastrophic	Occasional
14	Expiry date is passed in the stocks and the product is sold	Using unsterile implants leads to local infection	Untreatable local infection and explantation	Catastrophic	Occasional
15	Packaging integrity and the sterility is lost during transportation	Using unsterile implants	Untreatable local infection and explantation	Catastrophic	Remote
16	Label artwork contains incorrect information or non-compliance between label and implant	Inappropriate implant insertion and sinus and nerve damage if longer implant is used	Bone Damage or extensive burn to mucous membrane	Serious	Occasional
17	Product labelling fades or is rubbed off	Wrong implant selection	Bone Damage	Serious	Remote
18	The blister or plump ring of the door is not easily opened	not a hazard but just a failure	Discomfort	Negligible	Remote
19	After opening the main capsule pack the implant drop down in the surgery tray	Sterility is lost	Untreatable local infection and explantation	Catastrophic	Improbable
20	The user would not follow the instructions to prevent foreseeable misuse	Unforeseeable misuse	Bone necrosis leading to implant Loss	Critical	Occasional
21	Using unsterilized surgical kit	might cause temporary health infection	Irritation/ Inflammation in local (Self Limited)	Minor	Remote
22	Incorrect drilling sequence or insertion technique	Low primary stability	Loss of implant	Serious	Remote
23	Incompatible final drill versus implant shape	Gap in the interface of bone-implant	Insufficient Primary Stability	Serious	Remote

24	Incompatible torque wrench versus implant	Overheating in bone-implant interface and tissue necrosis	Insufficient secondary stability	Catastrophic	Remote
25	Low fitting between implant and abutment gap	Loosening	Loss of prosthetic component (broken)	Serious	Improbable
26	Incompatible connection between implant and abutment (bigger implant)	Gap in the interface of abutment-implant	Microorganism infiltration into gap and local infection	Critical	Improbable
27	Incompatible connection between implant and abutment	Useless abutment	Discomfort	Negligible	Improbable
28	Tightening the abutment screw with a torque below the prescribed range	Screw loosening	Loss of prosthetic component (detachment)	Serious	Improbable
29	Tightening the abutment screw with a torque above the prescribed range	Screw fracture	Loss of prosthetic component (broken)	Serious	Occasional
30	Dropping components in the patient's mouth	The component might blind the air pass	Asphyxiation	Catastrophic	Remote
31	Material hypersensitivities and allergies	Osseointegration fails	Loss of implant	Serious	Remote
32	Infection in patient mouth because of incorrect healing technique	Infection	Delayed healing	Minor	Remote
33	Implanting while poor bone quality	Osseointegration fails	Insufficient primary and secondary stability	Critical	Occasional

Proposed Mitigations: In order to control the risks number 1, 2, and 3, there are two different solutions. The first one is the process control and the other one is QC (raw material QC and in-line QC). The former includes prevention of inaccurate purchase based on designed procedure for purchases. There should be a rating list for the suppliers based on the votes of QC supervisor, financial director and commercial manager. Then the commercial manager would be allowed to place an order from the qualified and well-known sources. To reduce the probability of occurrence of the mentioned risks, two categories of QC parameters are designed, the first category measures and controls the dimensions based on the drawing checklist, and the second category visually control the surface.

There are two mitigations to control the risk number 4 related to the CNC lubricant oil failure in cooling the tools. The first one is the process control to prevent high variation of temperature which reduces the probability of occurrence of hazardous situations. Another useful mitigation would be to have tighter QC on products and also CNC tools, which prevents the use of unqualified products and notifies the operator to change the tools which reduces the severity of this hazard. Similar to the importance of controlling the CNC unit temperature, since the accuracy of the visual measuring device is highly dependent on the temperature, the mitigation for risk number 7 should control the process. It means that in every time usage of the device the room temperature should be recorded in the QC form to validate the measured dimensions.

Also, for risks numbers of 8 and 10 the best mitigation is to often validate and routinely control the process.

For risks numbers 5, 6, 9, and 11 monitoring the process have been proposed together with in-line QC. In manufacturing line there are QC stations after washing/drying, sandblasting and before packaging the final product. All these stations are based on visual control by use of microscopes. On the other hand, since the sterility of packed product is very important because of the high severity of related harm, this risk is controlled by process control and also random quality control with a safety factor of 1.4 over the international standards. For instance, based on ISO 11137-1 the maximum interval of time between determinations of bioburden for our product shall be three months while every two months check have been proposed. However, some QC tests require expensive devices, so these kinds of tests are outsourced.

For example, residual sands between threads are identified in SEM test. Thus, in addition to QC and PC that reduce the probability of occurrence, the severity of harm should have been lowered. This way Al2O3 sand is prescribed to increase the biocompatibility. Focusing on the process control beside in-line quality control is valuable and in some situations PC is easier than QC. Since counting the particles in the package of final product is hard and time consuming, process control in clean-room is proposed instead of quality control of packaging. This mitigation for risk number 12 reduces both severity and probability since by controlling the process the probability of occurrence is reduced, and by setting a safety factor for accepted amount of particles in the air, the sterilization is with a better quality that reduces the infection severity.

Another group of risks are related to labelling and information supplied for the user (risks 16 & 17). Controlling the risks relat-

ed to labelling is much easier than manufacturing risks. Color coding of packages' door and information supplied to the user is proposed through two labels, one of them on the backside of the cartoon, and the other one inside the blistering pack. As previously emphasized, regarding the importance of sterility about the risk numbers 11 and 12, there are critical harms behind unsterile product.Therefore, double seal packaging with blister and sealing door was proposed to reduce the probability of loss of sterility during transportation (risk number 15). In addition, the sterility is assured for a definite time, which itself needs an expiry date for each product.

To control the risk number 14, the available stocks are systematically controlled in a detection and traceability process. This means that registering the batch number of expired products for invoicing is not allowed in the designed software. But, it is possible that the expiry date pass while the user stores the implant. For risk number 24, an adjustable torque wrench that slips when the preset torque is reached out is proposed. Thus, no extra torque will be applied to the implant.Grabbing the implant from capsule pack is prescribed to be done initially by driver with hand, and then tightening it with hand piece or torque wrench. Therefore, there is a risk of dropping implant or other components in the patient's mouth. To reduce the probability of this risk, a driver with high gripping force has been designed. In addition, the risks numbers of 20, 22, 28, 29, and 30 would be controlled by specific design of the surgical kit. The kit is color coded and the color-based process of drilling is defined for each implant diameter. To control the tightening torque, there is an adjustable automatic torque wrench which bans the applied torque rising from the set amount. Since the risk number 33 is a surgeon-related risk factor, there is no systematic solution to reduce the probability of the occurrence. Therefore, the product design should result in primary stability which is higher than the typical required amount. On the other hand, microroughness of the surface improves the osseointegration rate. Thus, the severity of the hazardous situation is controlled to increase the relevant primary and secondary stability.

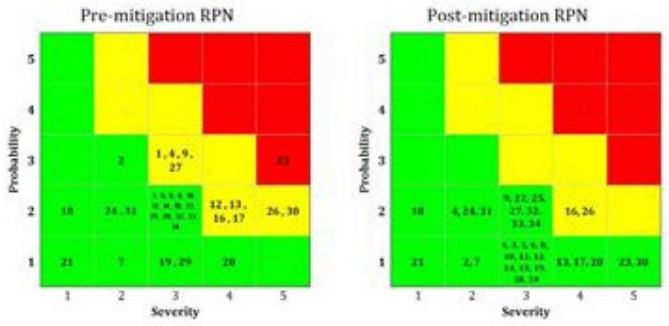

Figure 3: The RPN graph before and after applying mitigations

Based on the above results of Figure 3, pre-mitigation and post-mitigation overall accumulated risk values, there is a relatively acceptable advancement on compensating the risks. All the identified risks factors are mitigated and moved to the acceptable and conditionally acceptable range. Figure 4, is showing the difference on the RPN number before and after appropriate mitigations.

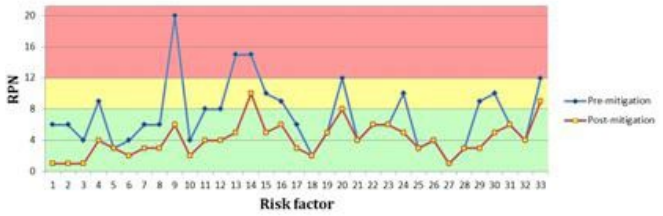

Figure 4: the difference between RPN number for all the listed risk factors. The background red color shows the unacceptable criteria, the background yellow color shows the conditional acceptance margin and finally the risks in the green region are risks in the accepted region

Discussion

Through a complete risk management activity composed from risk analysis, risk evaluation, risk control, residual risk evaluation and production and post-production information this study has been performed. To complete the risk analysis, first of all, the identifiable risk factors (all the considered risk factors are directly or indirectly related to the final product quality) are gathered and listed. The risk value of each factor is then evaluated based on the severity and the frequency of occurrence on three categories, which are pictorially illustrated on Figure 3. The results of the residual risk factors after applying appropriate measurement are provided in Figure 1 and Figure 2. Different types of risks of the failure of the products, and also the procedures are included in this study. After finishing a complete risk management activity composed from risk analysis, risk evaluation, risk control, residual risk evaluation and production and post-production information this study has been reported.

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