2014 3rd International Conference on Environment, Chemistry and Biology
IPCBEE vol.78 (2014) © (2014) IACSIT Press, Singapore
DOI: 10.7763/IPCBEE. 2014. V78. 18

Risk Management of the New One Piece Dental Implant

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Abstract. Risk management is the identification, evaluation, and prioritization of risks followed by coordinated and economical application of resources to reduce and control the probability and impact of unfortunate events or to maximize the realization of opportunities. For medical products sold in the European Union, EN ISO 14971 gives tools and methods for manufacturers to analyze and manage the risks associated with their products. This study discusses a new one piece dental implant based on ISO 14971 to optimize the safety and performance of the new design.

Keywords: risk analysis, risk management, one piece dental implant, ISO14971.

1. Introduction

The two piece dental implant was developed to be utilized in two step treatment. The implant is implanted into the bone level after raising a soft tissue flap, which is used to cover the implant during healing. When the implant and jawbone have fused together, a new flap is raised and a transmucosal abutment is screwed onto the implant to allow the prosthesis to be connected [1]. However, the two step procedure with a submerged healing period would not be essential. Implants can be placed with an immediate prosthetic loading protocol without compromising osseointegration [2]-[4]. The one piece implant is designed for direct placement in fresh extraction sockets. The surgical protocol for placement of this implant includes both flap and flapless procedures. The flapless benefits are less post-operative bleeding, surgery time, healing time, and more comfort for the patient [5], [6].

The inherently risky nature of medical products, especially those that come into contact with critical systems, means that manufacturers must thoroughly analyse their product risks against many factors. Risk management will help manufacturers identify hazards, prevent misuse, and estimate the risks for each hazard to better control and minimize these hazards [7].This study aims to show the result of risk management in our new developed one piece dental implant.

2. Materials and Methods

The following section including text and diagram is directly referenced from ISO 14971 [8]. This standard mentions a process for a manufacturer to identify the hazards associated with medical products, including in vitro diagnostic medical products, to evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of this standard are applicable to all stages of the lifecycle of a medical product. This standard does not apply to clinical decision making or specify acceptable risk levels and requires that the manufacturer have a quality management system in place. This process includes the four main elements of risk analysis, risk evaluation, risk control, and production and post-production information. A schematic representation of the risk management process is shown in Figure 1. The individual elements of risk management can have varying emphasis according to the specific life cycle

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phase. Additionally, risk management activities can be performed iteratively or in multiple steps as appropriate to the medical product.

2.1. Risk analysis

Risk analysis shall be performed for the particular medical product as described in step 2.1.1 to step 2.1.3. The implementation of the planned risk analysis activities and the results of the risk analysis shall be recorded in the risk management file. In addition to the records required in step 2.1.1 to step 2.1.3, the documentation of the conduct and results of the risk analysis shall include at least the following: a description and identification of the medical product that was analysed; identification of the persons and organization who carried out the risk analysis; and scope and date of the risk analysis.

2.1.1. Intended use and identification of characteristics related to the safety of the medical product

Identify and document those qualitative and quantitative characteristics that could affect the safety of the medical product and, where appropriate, their defined limits.

2.1.2. Identification of hazards

Compile documentation on known and foreseeable hazards associated with the medical product in both normal and fault conditions.

2.1.3. Estimation of the risk(s) for each hazardous situation

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation shall be considered and the resulting hazardous situations shall be recorded.

2.2. Risk evaluation

For each identified hazardous situation, the manufacturer shall decide, using the criteria defined in the risk management plan, if risk reduction is required. If risk reduction is not required, the requirements given in step 2.3.1 to step 2.3.5 do not apply for this hazardous situation (i.e., proceed to step 2.3.6).

2.3. Risk control

When risk reduction is required, risk control activities, as described in step 2.3.1 to step 2.3.6, shall be performed.

2.3.1. Risk control option analysis

The manufacturer shall use one or more of the following risk control options in the priority order listed: (a) inherent safety by design; (b) protective measures in the medical product itself or in the manufacturing process; (c) information for safety.

2.3.2. Implementation of risk control measure(s)

The manufacturer shall implement the risk control measures selected in step 2.3.1. Implementation of each risk control measure shall be verified. The effectiveness of the risk control measures shall be verified.

2.3.3. Residual risk evaluation

After the risk control measures are applied, any residual risk shall be evaluated using the criteria defined in the risk management plan. If the residual risk is not judged acceptable using these criteria, further risk control measures shall be applied (see step 2.3.1). For residual risks that are judged acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documents in order to disclose those residual risks.

2.3.4. Risk/benefit analysis

If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to step 2.3.5. For risks that are demonstrated to be outweighed by the benefits, the manufacturer shall decide which information for safety is necessary to disclose the residual risk.

2.3.5. Risks arising from risk control measures

The effects of the risk control measures shall be re-viewed with regard to: (a) the introduction of new hazards or hazardous situations; (b) whether the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures.

2.3.6. Completeness of risk control

Ensure that the risks from all identified hazardous situations have been considered. Compliance is checked by inspection of the risk management file.

2.4. Production and post-production information

Establish, document and maintain a system to collect and review information about the medical device or similar devices in the production and the post-production phases.

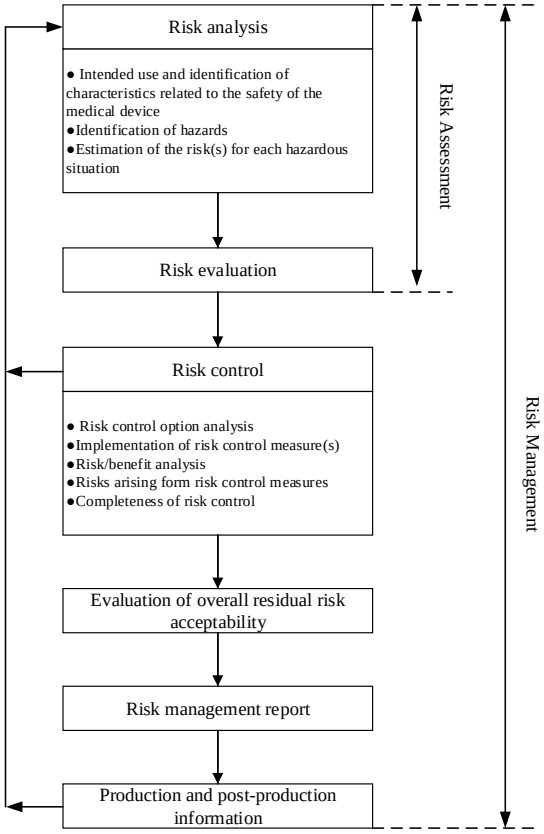

Fig. 1: A schematic representation of the risk management process

3. Results and Discussion

3.1. Results

This study follows ISO 17971:2007 for risk assessment of the new one piece dental implant. The process begins from identifying safety features, deciding impacts on safety and scoring the probability (see Table 1) and qualitative severity levels (see Table 2).

Table 1: Example of semi-quantitative probability levels

Common terms	Example of probability range	Scope
Frequent	$>10^{-3}$	5
Probable	$<10^{-3}$ and $\geqq 10^{-4}$	4
Occasional	$<10^{-4}$ and $\geqq 10^{-5}$	3
Remote	$<10^{-5}$ and $\geqq 10^{-6}$	2
Improbable	$<10^{-3}$	1

Table 2: Example of five qualitative severity levels

Common terms	Possible description	Scope
Catastrophic	Results in patient death	5
Critical	Results in permanent impairment or life-threatening injury	4
Serious	Results in injury or impairment requiring professional medical intervention	3
Minor	Results in temporary injury or impairment not requiring professional medical intervention	2
Negligible	Inconvenience or temporary discomfort	1

3.1.1. Questionnaire used to identify the new design characteristics that could impact on safety

Following ISO 14971:2007, the answers of the 40 detailed questions will be used to safety assessment of the new design.

3.1.2. New design assessment Procedure

The assessment procedure entails: Defining the functional requirements of the dental implant; simulating the failure mode in accordance with the functions; assessing its probability of occurrence and severity; and performing risk control. The risk level is a function of the probability and severity. User should maintain all risk levels to be under 9 points.

3.1.3. Identify failure modes and risk control functions of the new design

This new design is a pre-angled one piece dental implant. It can be directly implanted into patent's oral cavity. It provides support, bite and talk functions after fixating artificial crowns. It is made of titanium alloy, with rough and fine thread on the root surface and etching and sandblasting process treatment. This can accelerate the growth of new bone and allow growth and fixation of gums on the implant. The pre-angle is designed for easy assembly with canine crowns. Tables 3 and 4 are the evaluation results of the functions in accordance with the requirements specifications for risk analysis of the new design.

Table 3: Function failure of the one piece dental implant

Failure mode	Fixed Function	Positioning Function	Cover Function
Severity	3	3	3
Probability	3	3	3
Risk Level	9	9	9
Risk Assessment	Thread size error /Surface process program	Thread shape and number error	Crown fit problem
Risk Control	Raise the level of quality control and the detection rate	Raise the level of quality control and the detection rate	Raise the level of quality control and the detection rate
Phase	Manufacturing	Manufacturing	Manufacturing
Acceptable level of residual risk	3	3	3

3.2. Discussion

All potential hazards have been identified and analysed for risk analysis. The risk levels of each hazard with unacceptable range (more than 9 points) have been remediated and lowered to an acceptable range. The benefits of the new one piece dental implant would be greater than the risks that may arise.

4. Conclusions

Artificial tooth implantation staff (dentists) require professional expertise, experience, education and training. Implant designers should consider the safety and manufacturing technology of the industry.

Moreover, the most important thing is to perform risk analysis, to control the residual hazards risk under an acceptable range. The evaluator proceeds in these four stages: (1) identify known hazards, estimate the risks arising from expected use or misuse; (2) minimize the risk by safety design and manufacturing; (3) take appropriate steps to reduce the residual risk as much as possible; (4) inform users of the residual risk.

Table 4: Equipment characteristics of the hazard sources

Failure mode	(Implantation) (Side effects) (Complications)	Physiological suited of patients Loss of clinical effective and safety	Incompatibility of the biological material
Severity	5	3	5
Probability	4	3	1
Risk Level	20	9	5
Risk Assessment	Surgery performed by a doctor; Each step should have a safety alert to help the doctor to evaluate	After implantation, probably loss the clinical effective due to personal exercise habits	The Sources of material and components should confirm
Risk Control	Doctors assess the risk of the patient in by the instructions	There are a variety of implant sizes, according to patient characteristics, carefully evaluate the types of specifications	Material properties are consistent with the standard
Phase	Surgical stage	Usage phase	Manufacturing phase
Acceptable level of residual risk	5	3	5

5. Acknowledgements

This work is supported by the ComMed Technologies Co., Ltd. Thanks for Michael Chang (macst34@gmail.com) for proofreading services.

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