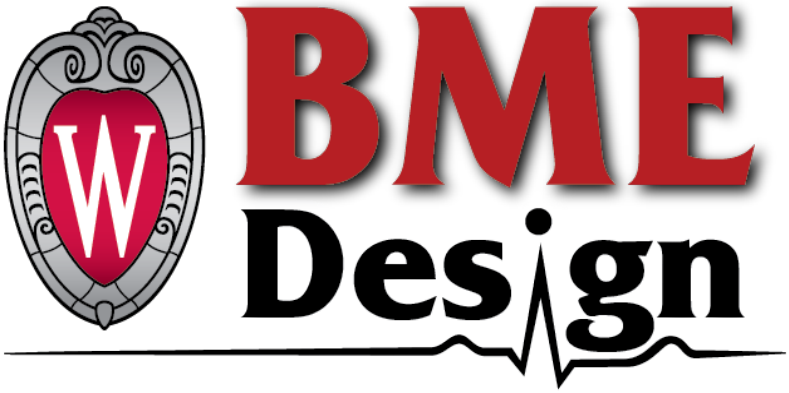

Lock Washer for Dental Implant-supported Restorations

Preliminary Product Design Specifications

BME 200/300

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Function:

Dr. Tipple uses the implant placement technique called the screwmentable. This technique allows the abutment and crown to be screwed directly into the implant through a passageway in the crown. This allows Dr. Tipple to adjust the crown as needed checking lateral, left and right occlusions and clench tests before the passageway is filled and sealed. The screw holding the abutment to the implant can become loose through everyday occlusal forces such as chewing. Adding a lock washer to the screw would sustain the 35 Ncm torque that is applied to the screw when placed in the implant. The lock washer is able to apply spring tension to keep the screw from loosening [1].

Client requirements:

- Lock washer must be fixed onto the screw
- Lock washer design must work with the current screw that Dr. Tipple uses in practice
- Titanium is the ideal material

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

1. The device will be in constant use once implanted in the mouth.
2. The washer and screw must constantly maintain tightness in the implant.
3. There will be a constant normal force on all sides of the screw from the antagonist tooth and the implant. There will also be shear forces on the threads of the screw from the implant.

b. *Safety*:

1. The correct material must be used to ensure biocompatibility.
    a. Typically either a titanium alloy or zirconia is used.
2. The FDA sets regulations for dental implants and implant accessories. These

regulations largely enumerate different tests the implant must be able to withstand to be safe and effective when in use. Examples include, the ability to withstand compressive and shear loads, biocompatibility, appropriate corrosion rate, compatibility in an MR environment, and more [2].

c. *Life in Service*:

1. On average, dental implants last 10-15 years within the mouth [3]. The lock washer should withstand continuous oral use without deterioration and prevent the screw from loosening for at least ten years [4].

d. *Shelf Life*:

1. Titanium, the most common metal used in dental restoration, has a shelf life of 10-25 years [5]. The durability of the titanium depends on storage and care.

e. *Operating Environment*:

1. Dental Screws are typically stored in small containers without specific protection measures. As a result, the lock washer will need to withstand corrosion and rusting in temperatures between 20℃ and 24℃ and under humidity levels between 20 and 60% [6].
2. The lock washer must withstand a range of factors from exposure to the mouth. These factors include food substances, bacteria, saliva, blood, vibrations from speaking, and contact with teeth. In terms of pressure, the lock washer must be able to withstand forces of 50-800 N from the force exerted by the human jaw [7].

f. *Ergonomics*:

1. The screw and lock washer should be easy to handle. The client should be able to easily identify when the screwdriver has been securely locked into the screw, making the installation process more manageable.
2. The screw should have a torque of 35 NCm to fit securely in the abutment.

g. *Size*:

1. The client most likely uses a narrower screw with a 3.5 mm diameter and one that is wider for molars that is 4.6 mm in diameter [3].
2. The thickness of the washer should be between 1 to 2 mm in thickness, have roughly a 2 mm inner diameter, and a 2.5 mm outer diameter.
3. The lock washer must be slightly smaller in diameter than the threads on the screw so that it is not able to slip off. Likely, the washer will be placed on the screw before creating the threads.

h. *Weight*:

1. The weight will ultimately depend on the selected materials used in different prototypes, and will likely remain under half a gram due to the size.

i. *Materials*:

1. Titanium has proven to work more effectively than alloys of titanium in preventing screw loosening, but zirconium is often used as well [8]. Titanium has many dental applications due to its biocompatibility, osseointegration, and corrosion resistance [9].
2. The final product should be made of a metal, but prototypes will likely be made of materials that can be used in 3D printing, such as nylon or ABS as they tend to be stronger [10].

j. *Aesthetics*, *Appearance, and Finish*:

1. Washers with a rougher surface texture exhibit better performance when it comes to preventing screw loosening [8].
2. Unlike a normal washer, a lock washer splits in the middle of the circular shape, creating friction between the two parts and preventing loosening over time due to vibration [11].
3. The final prototype's finish will be metallic, and potentially gold coated (screw and washer) as that leads to better stability [12].

2. Production Characteristics

a. *Quantity*:

1. The client requires a single final prototype, however, the design should be able to be mass produced.

b. *Target Product Cost*:

1. The client did not outline a specific budget, but he is willing to spend however much is needed to produce several prototypes and a lock washer made of a reliable material. Due to the size of the final design, the team anticipates spending a fraction of the available budget.
2. A single titanium lock washer that has an inside diameter of 2 mm and would securely fit around an implant screw costs $3.19 [13].

3. Miscellaneous

a. *Standards and Specifications*:

1. Standards
    a. Standards for dental screws fall under the 11.060.15 Dental Implants category by the International Organization for Standardization (ISO) [14].
    b. ISO/TR 18130:2016 Dentistry - Screw loosening test using cyclic torsional loading for implant abutment connection of endosseous dental implants [14].
        i. This test is most appropriate for evaluating new types of joints held by screws. The report provides a protocol for cyclic torque on an implant abutment joint, and is intended for prefabricated implant bodies, implant abutments and implant connecting parts that are made of metallic materials [14].
2. FDA
    a. Dental implants, screws and abutments fall under FDA Class II

regulation [2].

i. Code of Federal Regulations citation: 21CFR872.3640 [2].

ii. Must meet the Class II special controls requirements.

b. *Customer*:

1. Dr. Donald Tipple has had many years of experience with implants. He has noticed a few issues with the current design aside from the loosening of the screw. He does not like how the current design of the screw is difficult to use in the mouth. This is because it is difficult to line up the screwdriver with the head of the screw. Although the project focuses mainly on avoiding the loosening of screws, creating small adjustments that allow more ease of implantation would be ideal to optimize our design.
2. The customer likes the current material, which is typically titanium or a titanium alloy.

c. *Patient-related concerns*:

1. It is important when using this device to be careful with the implantation, as poor technique can negatively affect the longevity of the device. The device also must be designed in a way that allows for a crown that is custom for the patient.
2. Lastly, it is important to take into consideration the discomfort that can be caused by the device. The client discussed how sometimes there can be discomfort when the screw loosens if the gums begin to grow over the implant.

d. *Competition*:

1. There are no current existing designs that include a lock washer on the screw. Some popular designs used in practice today are as follows.
    a. Currently there is a patented design where the screw has both a conical and cylindrical screw part. The two different shaped portions of the screw allow it to stay more locked in place [15]. This is a commonly used design in dentistry, as it works pretty well, however the screw does still become loose from

occlusal forces.

b. There is another patented design with a locking cap on the implant [16]. This design prevents loosening, however it requires the use of an additional piece which is not as desirable.
c. Another similar design has implant anchors to prevent the screw from loosening [17]. Like the one previously discussed, it requires an additional part, and it also does not fix the screw specifically, which is requested by the client.
d. One last design is a system for securing a dental implant that prevents it from coming loose [18]. This design also does not solely focus on the screw. It requires a lot of additional parts aside from the screw.

2. As outlined above, there is not a current design that attempts to solve this problem by focusing solely on the screw. Additionally, there is no design that utilizes a lock washer, which would not require additional steps for the dentist implanting the device.

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