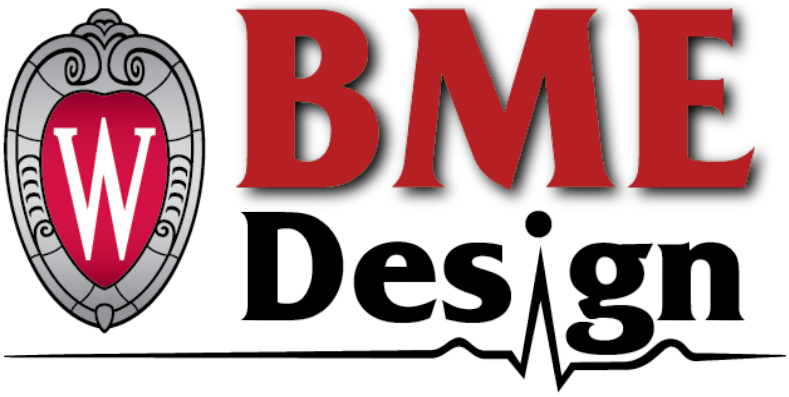

Lock Washer for Dental Implant-supported Restorations

Preliminary Report

BME 200/300

Client: Dr. Donald Tipple
Advisor: Dr. John Puccinelli

Team Members:
Maggie McDevitt (Co-Team Leader)
Isabelle Peters (Co-Team Leader)
Aaron Marattil (Communicator)
Caroline Davis (BSAC)
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11 October 2023

Abstract:

Gum disease, tooth decay, injuries, or genetic conditions could all lead to a missing tooth. Dental implants are the preferred option to replace a single tooth or multiple teeth in different spots. This treatment option involves surgically implanting a post or frame into the jaw to replace the root, creating a permanent base for a replacement tooth. An abutment, which is cemented to the crown or fake tooth, is attached to the post via a screw. The most common issue with this method is that the screw loosens after a period of time; the abutment then must be removed and retightened by the dentist, which can be uncomfortable for the patient as the gums begin to move. The proposed solution is to add a lock washer on the screw to prevent the abutment from becoming loose, which currently is not used. A titanium alloy is the preferred material that will be used by a company to 3D print a split lock washer. It will be determined whether or not a lock washer is beneficial when combined with the current dental implant method. The amount of torque required to remove the screw from the post will be statistically analyzed and compared to the torque needed to remove it while it is attached to the lock washer.

Table of Contents

Introduction and Background

Dr. Donald Tipple has almost thirty years of experience with implants, and has noticed a few issues with the current design aside from the loosening of the screw. He dislikes how the screw is difficult to use in the mouth, as 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.

Studies have shown that around five percent of dental implants fail [1]. While this is not a large amount, replacing the abutment and crown can be tedious and require additional work for the dentist. Dental implants can fail from occlusal forces from everyday use. The loosening of the implant can also cause discomfort for the patient, as it is possible for gums to grow between the part implanted into the jaw, and the screw that the crown is attached to. When the gum grows it can become pinched between these two parts and cause discomfort for the patient.

A common design that is currently used is called the screwmentable. It features a small screw that screws into the implant with an abutment, which is what the crown is designed around [2]. While this piece has worked well, there are still many cases where the screw comes loose. In order to improve this, a system will be implemented to decrease the number of loosened screws, and save both the dentists and patients time. Current designs that intend to prevent loosening often involve the use of many additional pieces which end up taking more time for dentists in the long run. A patented design uses a locking cap to prevent loosening [3]. While this does a good job of securing the screw in place, It requires an extra piece, and therefore is more work for the dentist implanting the crown.

It is essential that dental implants are made from a biocompatible material. Because of this, the implants are commonly made from titanium, a titanium alloy, or zirconia. The goal is to design a solution that allows the screw to be securely in place for a minimum of 15 years.

Preliminary Designs

Split Lock Washer	External Tooth Lock Washer	Conical Washer

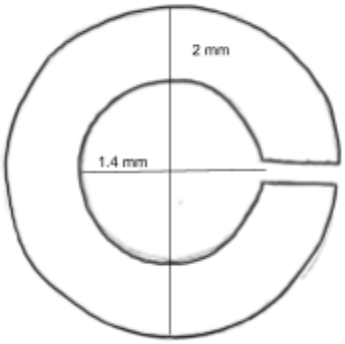


***Figure 1**: Aerial profile of split lock washer*

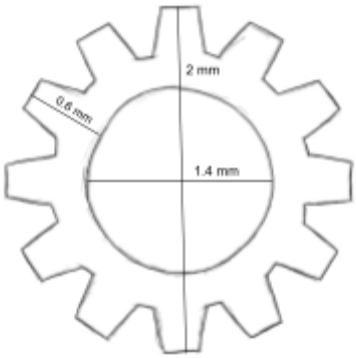


***Figure 2**: Aerial profile of external tooth lock washer*

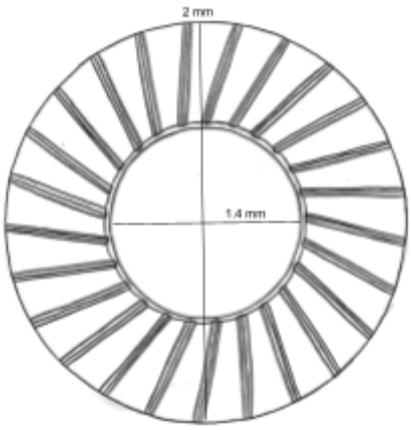


***Figure 3**: Aerial profile of conical washer*

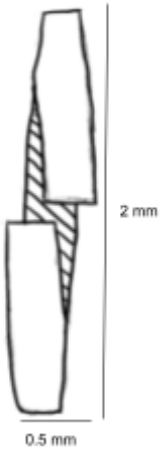


***Figure 4**: Side profile of split lock washer*

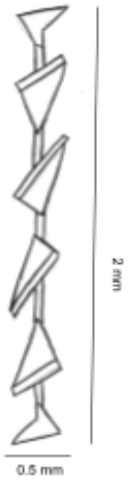


Figure 5: Side profile of external tooth lock washer

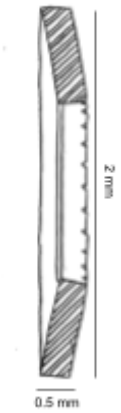


***Figure 6**: Side profile of conical washer*

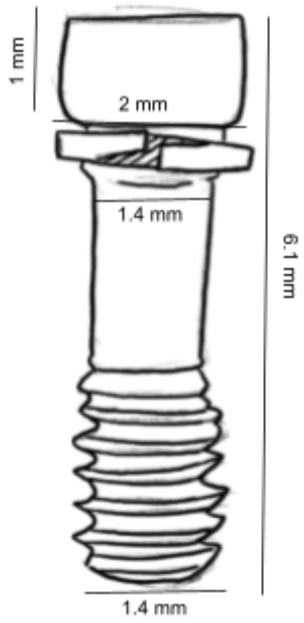


***Figure 7**: Split lock washer on the dental screw*

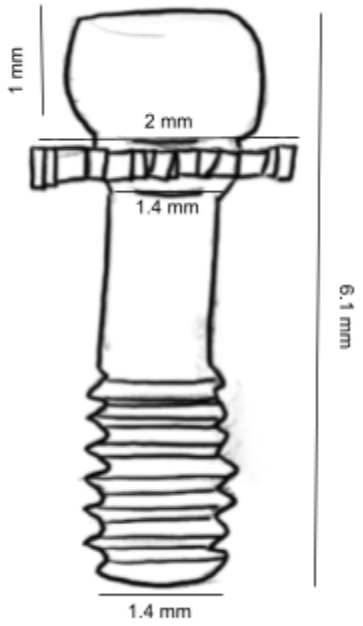


***Figure 8**: External tooth lock washer on the dental screw*

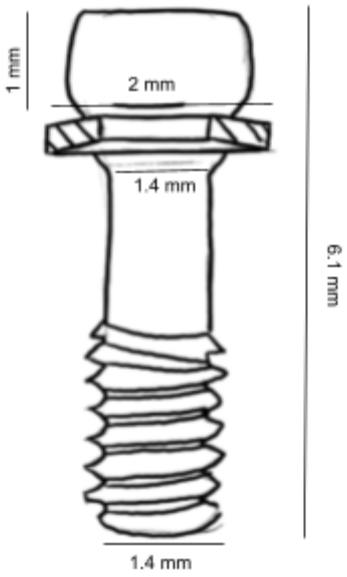


***Figure 9**: Conical washer on the dental screw*

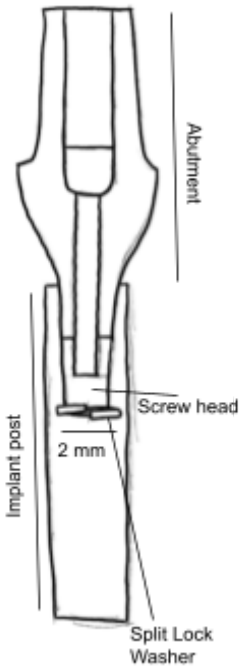


***Figure 10**: Split lock washer placement in dental implant*

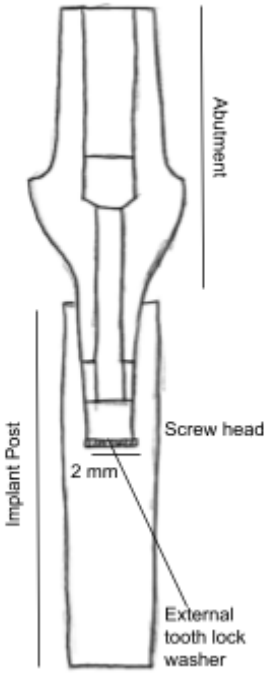


***Figure 11**: External tooth lock*

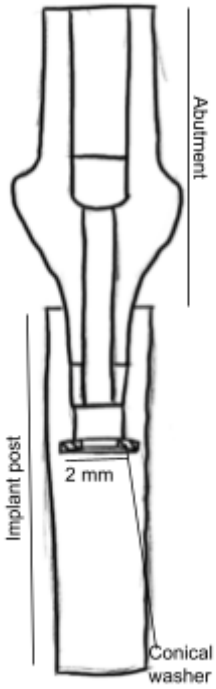
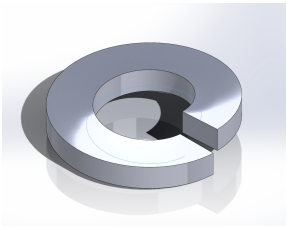
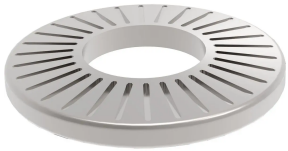


***Figure 12**: Conical washer*

	washer placement in dental implant	*placement in dental implant*
This design is a split lock washer characterized by the split in the metal ring. The split creates an elevation, with one side of the washer being higher than the other. The unlevel surface creates compression when the screw is fastened. This compression pushes against the joint so the threads remain in place during vibrations, effectively preventing loosening.	This design is an external tooth lock washer. It is characterized by its outward-facing teeth, which are used to bite into the surface surrounding the screw. The external tooth lock washer has the best locking efficiency since the teeth are on the outside, providing more resistance to torsion. This design works best on large screws.	This design is a conical washer. It is characterized by its convex disc shape, which is supported by force from the exterior and center of the disc. As a result of the design, there is minimal movement during the compression process. Conical washers can maintain high tension, making them effective shock absorbers that keep assemblies tight.

Preliminary Design Evaluation

***Table 1**: Design Matrix for Type of Washer*

Criteria (Weight)	**Split Lock Washer**  ***Figure 1:** Split Lock Washer*		**External Tooth Lock Washer**  ***Figure 2:** External Tooth Lock Washer [4]*		**Conical Washer**  ***Figure 3:** Conical Washer [5]*	
Resistance to Torque (40)	4/5	32	3/5	24	3/5	24
Versatility (25)	5/5	25	1/5	5	4/5	20
Ease of Fabrication (20)	4/5	16	4/5	16	4/5	16
Safety (10)	4/5	8	3/5	6	4/5	8
Cost (5)	5/5	5	4/5	4	3/5	3
Total (100)	86		55		71	

The spring lock washer is highly resistant to torque as well as vibration and works well with small screws like what would be used in this project [6]. They are also the most versatile since their size can be easily scaled unlike other designs and, as previously stated, they work with small screws [7]. All the designs will likely be fabricated by a 3D printing company that uses titanium, making them equally as difficult to fabricate. All the designs are quite safe, however, there was concern that the teeth on the external tooth lock washer could break off and cause problems, as well as a loss in production [8]. Additionally, the conical washer requires more material which would increase its cost. The split lock washer has none of these issues.

***Table 2**: Design Matrix for Washer Material*

Criteria (Weight)	**Pure Titanium**		**Titanium Alloy**		**Zirconia**	
Strength (40)	3/5	24	5/5	40	4/5	32
Longevity/ Durability (25)	4/5	20	5/5	25	3/5	15
Biocompatibility (15)	5/5	15	5/5	15	4/5	12
Safety (10)	4/5	8	4/5	8	5/5	10
Aesthetics (5)	3/5	3	3/5	3	5/5	5
Cost (5)	5/5	5	4/5	4	3/5	3
Total (100)	75		95		77	

Titanium alloy is the strongest and lasts the longest [9], [10], [11], [12], [13]. All materials are quite biocompatible, however, titanium and titanium alloys osseointegrate much better [12]. While all materials are quite safe, zirconia is usually considered the safest as it limits metal to metal interactions within the system [13]. Zirconia is the most aesthetic material, as zirconia implants are 100% white, hypoallergenic, and do not corrode [14]. It blends better with the gums and makes them almost invisible, creating a fully natural look. Pure titanium is the cheapest followed by a titanium alloy, and lastly, zirconia [17], [18], [19].

Proposed Final Design

The proposed final design is a Split Lock Washer made of Titanium Alloy.

Fabrication/Development Process

Materials

Titanium Alloy: An alloy that contains mostly titanium metal along with other chemical elements. In dentistry, beta titanium alloy is used most commonly. Other possible elements used in this alloy are zirconium, niobium, vanadium, iron, aluminum and manganese. This beta alloy is used in dentistry primarily because of its strength and elasticity ratios being much higher than those of some sort of steel or other metal.

The current titanium alloy screw Dr. Tipple uses is called Titanium-6aluminum-7niobium alloy (TAN). It contains 6.50-7.50 % mass niobium, 5.50-6.50 % mass aluminum, less than 1.09 % mass of other residuals (Ta, Fe, O, C, N, H) and the rest of the mass in titanium.

Methods

In order to create a prototype of the split lock washer on the dental implant screw, a lock washer will be ordered with the specific design dimensions and material from a company– either Protolabs located in Minnesota or Sculpteo located in France– to 3D print it. Both companies are able to provide a quote after a STL file is uploaded. Based on the initial evaluations from both companies, we will then work with the company that provides a better fit in terms of cost, timeline, ease of fabrication, and access to the desired metal.

Testing

In order to evaluate the ability of our prototype's performance on sufficiently keeping a dental implant screw in place by maintaining a torque of 35 Ncm, torque tests will be performed. The amount of torque required to remove the screw without a washer will be used as a control and compared to the amount of torque needed to remove the screw with a washer. The BME department has an FSB2 torque testing device that has a resolution of .001 Nm to 10 Nm [20]. However, the sample diameter range starts at 1.5 mm, so additional samples may have to be ordered or created with diameters at least 0.1 mm larger to be able to use this device.

Discussion

While implementing a lock washer as part of the implantation procedure does not have many direct ethical considerations, metal dental implants being inserted into the gum as a tooth root is controversial to some dentists. It can be viewed as the cheap and easy way to solve a dental issue, as opposed to doing a bone graft [18]. However, there are also many people without dental insurance who cannot afford dental implants, and that needs to be taken into account as well. Ultimately, the patient's personal and religious values cannot be neglected when considering

treatment options as patient autonomy is expected. The American Dental Association Principles of Ethics and Code of Professional Conduct also outlines that dental providers obligate moral commitment towards the welfare of their patients; each patient presents a slightly different case, and it must be individually treated as such [22].

Conclusions

The main goal of the project is to design a solution that prevents dental implants from loosening over time. Occlusal forces, such as chewing and grinding teeth can cause the dental implants to loosen over a long period of time. Although dental implants rarely loosen, it is inconvenient for the dentists to remove the abutment to re-tighten it. Additionally, the loosening of the screw can cause discomfort for the patient because their gums can grow between the gap that is formed, and cause discomfort for the patient as their gums can be pinched. In order to combat this problem, a lock washer will be placed on the screw that engages the screw, and makes it less likely to loosen. The ideal design for this will be a split lock washer, and ideally it will be made from a titanium alloy. The titanium alloy will have the highest torque resistance, and is also biocompatible.

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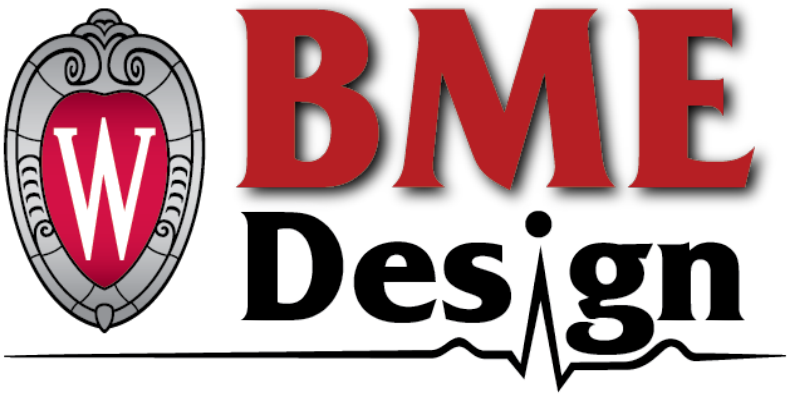
Appendix A: Product Design Specifications



Lock Washer for Dental Implant-supported Restorations

Preliminary Product Design Specifications

BME 200/300

Client: Dr. Donald Tipple
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Team Members:
Maggie McDevitt (Co-Team Leader)
Isabelle Peters (Co-Team Leader)
Aaron Marattil (Communicator)
Caroline Davis (BSAC)
Jacki Szelagowski (BWIG)
Kennedy Young (BPAG)

22 September 2023

Function:

Dr. Tipple and many dentists worldwide use the dental implant placement technique called the screwmentable. This technique allows the abutment, or fixture that is placed between the implant post and the crown, to be screwed directly into the implant through a passageway in the crown [1]. 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. As the screw is installed a 35 Ncm torque is applied to keep it in place. The lock washer would be placed on the screw threads before it is inserted into the implant to apply spring tension to maintain this torque and keep the screw from loosening [2].

Client requirements:

- Lock washer must be fixed onto the screw.
- Lock washer design must work with the current Straumann 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 for up to fifteen years 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 material must ensure biocompatibility; 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 [3].

c. *Life in Service*:

1. On average, dental implants last 10-15 years within the mouth [4]. The lock washer should withstand continuous oral use without deterioration and prevent the screw from loosening for at least ten years [5].

d. *Shelf Life*:

1. Titanium, the most common metal used in dental restoration, has a shelf life of 10-25 years [6]. 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 under humidity levels between 20 and 60% and in temperatures between 20℃ and 37℃ as it will be in the mouth and stored at room temperature [7].
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 [8].

f. *Ergonomics*:

1. The screw and lock washer should be easy to handle. The dentist should be

able to easily identify when the driver has been securely locked into the screw, making the installation process more manageable. The driver should be less than 4 mm wider than the screw and should match the insertion shape of the screw [7].

2. The screw should have a torque of 35 Ncm to fit securely in the abutment.

g. *Size*:

1. The dentist uses a narrower screw with a 1.4 mm shaft diameter. The whole screw is 6.1 mm long, and the screwhead makes up 1 mm of that length. The screwhead is slightly wider than the shaft with a 2 mm diameter.
2. The washer should have an inner diameter of 1.4 mm so that it is unable to move around.
3. The lock washer must be slightly smaller in its inner 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 zirconia is often used as well [9]. Titanium has many dental applications due to its biocompatibility, osseointegration, and corrosion resistance [10].
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 [11].

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

1. Washers with a rougher surface texture exhibit better performance when it comes to preventing screw loosening [9].
2. Unlike a normal washer, a split lock washer breaks in the middle of the circular shape, creating friction between the two parts and preventing loosening over time due to vibration [12].
3. The final prototype's finish will be metallic, and potentially gold coated (screw and washer) as that leads to better stability [13].

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 $200-$300 to produce several prototypes and a lock washer made of a reliable material. Due to the size of the final design, it is anticipated that a fraction of the available budget will be spent.
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 [14].

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) [15].
    b. ISO/TR 18130:2016 Dentistry - Screw loosening test using cyclic torsional loading for implant abutment connection of endosseous dental implants [15].

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 [15].

2. FDA
    a. Dental implants, screws and abutments fall under FDA Class II regulation [3].
        i. Code of Federal Regulations citation: 21CFR872.3640 [3].
        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 [16]. 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 [17]. 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 [18]. 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 [19]. 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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Appendix B: Material Expenses Sheet

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
LabArchives Notebook	For Documentation purposes	LabArchives	N/A	9/8/23	1	$15	$15	BME Design-Fall 2023 - Maggie MCDE VITT - LabArchives, Your Electronic Lab Notebook
Steel Split Lock Washer	One with an inner diameter of 2.8 mm, and the other with a much larger diameter for presentation purposes	N/A - purchased from Makerspace	N/A	10/5/23	2	$0.10	$0.20	N/A
3D Printed PLA Split Lock Washer	Inner diameter of 5 mm, made of plastic and on a small support	Makerspace 3D printer	N/A	10/5/23	1	Free	Free	N/A