‘A comparison of a proprietary and generic dental implant abutment connection using computerised microtomography (micro-CT).

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Contents

Abstract

Aim: To observe and assess the internal characteristics of a dental implant by comparing and contrasting the abutment-implant connection of a proprietary abutment connected to this implant and a generic abutment connected to this same implant.

Materials and Methods: Fourteen implant specimens (Neoss Dental Implants, North Yorkshire, UK) were used in total across two groups. Seven proprietary titanium abutments were connected to seven corresponding implants with a proprietary abutment screw (proprietary group); seven generic titanium abutments were connected to the remaining seven implants by a proprietary abutment screw (generic group). Specimens were scanned using computed microtomography (Skyscan 1076: Bruker microCT, Kontich, Belgium) and analysed qualitatively using processing software (Avizo 9.0: FEI, Oregon, USA).

Results: Proprietary implant-abutment connections were shown to be closely adapting, with no evidence of marginal gap horizontally or vertically. The unique Neoss implant-abutment connection contacts in half as many places as the generic implant-abutment connection. Generic implant abutment connections displayed marginal discrepancies in all seven specimens.

Conclusion: Within the limitations of this study, proprietary abutments demonstrated a superior fit compared with generic abutments. Marginal discrepancies between generic abutments and implants may have been reduced if implant replicas were not used as a starting point.

Declaration

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Signed by: _____

Benjamin R Sellick

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Chapter 1

1.1 Introduction

Dental implants, and the prostheses retained or supported by them, form the cornerstone of contemporary dental practice and tooth replacement. Their importance as a treatment alternative has increased since their integration into dental practice, with their increased uptake the result of improvements in engineering, materials technology, and surgical techniques.

For this study, a group of prominent implant manufacturers were contacted in writing requesting their voluntary participation in the study. Of these manufacturers, Neoss Australia accepted the study proposal and assisted with supply of proprietary implant componentry for the purposes of the study. The proposal acceptance by Neoss Australia was quite fortuitous, as it permitted the analysis of one of the more unique implant-abutment interfaces.

There exists no consensus on nomenclature regarding manufacturers of dental implants, their componentry or their connections. Non-proprietary components have been referred to in the dental literature, and within marketing material at times, using a variety of terms: third-party, generics, clones, copies, pirate, substitutes and generic to name a few. [1-3] For the purposes of this study, we have chosen to use the term “generic” to describe those components that have not been manufactured or licensed by the company that has produced the implant fixture itself.

Fourteen implant specimens from Neoss Australia were used in the study [Neoss ProActive Bimodal Ref: 21136], with Neoss being an implant fixture of proprietary origin. In addition, seven proprietary titanium abutments were obtained from the same company, Neoss Australia. An additional seven abutments were obtained from a generics manufacturer, Stoneglass Industries, who were tasked with producing an abutment to fit a proprietary laboratory replica provided by Neoss Australia.

This methodology was deemed to be anecdotally similar to how a number of generic manufacturers produce implant componentry for sale and thus was an attempt at producing a real-world scenario encountered by clinicians.

Economic pressure to produce and deliver implant- supported reconstructions at a reduced materials cost may lead to the acceptance of alternative solutions, ie- the involvement of generic abutments, that currently are readily available on the market. Limited access to equipment and reduction of investments in the dental laboratory could also result in the selection of generic abutments. However, the design of screw joints such as those at the implant-abutment interfaces should be matched carefully, as the biomechanical properties of the construct depend to a great extent on factors such as materials, tolerance, connection design, and preload.[3]

Generic abutments may differ in the design and appearance of connecting surfaces, shape, dimensions, and material and have been described as having

higher rotational misfit. All of these differences may result in unexpected failure modes and potentially have an adverse effect on clinical handling as demonstrated in previous studies[3]

In a recent study examining the connection between proprietary abutments and generic implants, the degree of misfit was approximately 50% of that observed with generic abutments produced for implants from two other manufacturers[2]. It was concluded that the connection of NobelProcera zirconia abutments with other implant systems resulted in a higher vertical misfit at the implant-abutment interface compared to the original connection.

Under the banner of implant dentistry, the concept of "not-fitting" or "misfit" has the potential to refer to a wide variety of issues. As an example, misfit may perhaps arise as a result of a particular manufacturing process; or it may simply be the outcome of an inappropriately chosen clinical technique. The individual biological and mechanical coupling on all levels that occurs during implant therapy is a complex matrix influenced by a multitude of factors. It is the intention of this literature review to identify and address these factors and their effects as they pertain to misfit, noting how they may or may not influence the fit of components with both clinical and empirical ramifications.

Any misfit, whether vertical or horizontal is able to apply a load to the implant assembly and the surrounding bone. This has been directly related to several mechanical complications, such as loosening or fracture of abutment and prosthetic screw, abutment fracture and complete loss of osseointegration in the most severe cases.[2]

Although the optimum level of accuracy of fit at the implant-abutment interface has yet to be determined, some authors claim that controlling the amount of misfit is important to prevent mechanical and biologic failures, as well as to maintain osseointegration. [2] However, as yet the clinical implications of misfit remain unclear.

1.2 Aims of the Study

The aims of the study were are as follows:

General Aim:

- To compare qualitatively proprietary and generic dental abutment connections using computerised microtomography (Micro-CT)

Specific Aims:

- To observe and assess the internal characteristics of the Neoss ProActive Implant (Neoss Dental Implants, North Yorkshire, UK)
- To observe and assess the connection between the Neoss ProActive implant and a stock titanium abutment (NeoLink™, Neoss Dental Implants, North Yorkshire, UK)
- To observe and assess the connection between the Neoss ProActive implant and a generic titanium abutment

Chapter 2 Literature Review

2.1 Introduction

When considering the replacement of missing teeth with dental implant-supported (implants) prostheses, clinicians can be confident that the treatment of patients using established techniques is predictable and well documented. The successful restoration of implants from a prosthodontic point of view, while well established in the literature, is widely dependent upon a number of factors. These can be generally categorised as either biological or mechanical in origin[4].

Dental implants are a safe and predictable treatment modality for the replacement of teeth[5-7]. Despite a wider range of options available in modern practice, it is interesting to note that osseointegrated implants were originally proposed as a replacement for complete edentulism, with early studies conducted using animal specimens[8,9]. The edentulous patient of the time was treated with removable complete dentures, irrespective of their denture wearing experience, dental history or desire[5]. If these prostheses were unsuccessful in their capacity to restore edentulism, there was very little available at the time in terms of treatment alternatives.

The psychological impact of tooth loss however, is an individual patient-determined oral health-related phenomenon[10]. Under circumstances where prostheses have been inadequate, there is not only a reduction in oral function that is endured, but rather the potential for a reduction in self-confidence[5]. Tooth-loss as an outcome, as it pertains to edentulism, has been reported to have a profound

impact on the lives of some individuals, giving rise to: bereavement; altered self-image; a dislike of appearance; an inability to discuss the issue of tooth loss; a concern about prosthodontics privacy; behaving in a way that keeps tooth loss secret; altered behavior in socialising and forming close relationships; premature ageing; and a lack of adequate preparation for the outcome of edentulism by the clinician[11]. These outcomes may even be present irrespective of whether a patient appears to be coping with removable dentures. Equally, the impact of any subsequent treatment to an individual's life is highly individualised[10] and as we strive to improve the oral health related outcomes for patients it is important to understand the basis of patient-specific issues that compel them to seek what is ultimately elective care of a chronic condition[10].

2.2 Predictability and durability of implant treatment

Considering implant therapy from a point of predictability and durability once more, we encounter terms such as success and survival. A discussion of success and survival in the context of implant therapy is not possible however without a definition as it pertains to the dental literature. Albrektsson felt that implant survival is often misquoted to indicate implant success[7], in reality however, the fixture needs only to be present in the jaws of the patient to indicate implant survival. A high survival rate statistic provides no information to the reader on the quality or function of the implant and is considered to be but one aspect of the predictability/durability equation. The definition of success in implant therapy is a far more complex parameter and is ultimately dependent upon the study conditions outlined by the authors. Commonly, success is reported from either a

patient or clinician perspective, or both. One author[12] proposed that success could be redefined as an absence of complications at follow-up or only minimal problems that might be dealt with simply.

Success criteria have evolved from early iterations that were comparatively utilitarian and focused primarily on the implant itself. These early criteria looked primarily at associated bone changes, with or without mobility, all without a consideration for symptoms. Beaumont[12] reports that during a 1978 NIH (USA) consensus conference, organized, convened, and moderated by Dr. Paul Schnitman and Dr. Leonard Shulman (co-directors of the Harvard Tooth Implant-Transplant Research Unit at the Harvard School of Dental Medicine) a report was released as a result. The conference proceedings stipulated bone loss about an implant be limited to no more than one third of the implant height and a restriction of mobility to no more than 1 mm in any direction[13]. Such generous criteria seems incredible from a contemporary context, but speaks volumes as to the evolution of success criteria in implant dentistry.

By 1979, a further consensus paper (by the 1978 editors) expanded upon the earlier criteria[14]. Schnitman and Schulman included clinical indicators that widened the focus to include structures beyond the periimplant bone: functional service for 5 years in 75% of patients; gingival inflammation amenable to treatment; absence of symptoms and infection; absence of damage to adjacent teeth; and absence of paraesthesia or violation of adjacent structures.

The Schnitman and Schulman paper stood for seven years and certainly catered to an increasingly patient-centric treatment approach. However in 1986, Albrektsson and colleagues published a success criteria that became one of the most widely accepted[15], proposing the following success criteria: lack of mobility; less than 1.5mm bone loss in the first year; no more than 0.2mm of vertical bone loss annually thereafter; no radiographic evidence of periimplant radiolucency; no radiographic evidence of violation of the mandibular canal; no history of pain, suppuration or paraesthesia. Furthermore, in the context of all these previous factors, a success rate of 85% at the end of a 5 year observation period and 80% at the end of a 10-year period be the minimum criteria for success[15].

A follow up paper by Albrektsson and Sennerby in 1991 mentions observations regarding success rate percentages within the historical literature and charted a discussion that points to implant therapy advancements. They maintained that while Schnitman and Shulman had asked for a minimum 75% success over a 5-year observational period, such a figure would be unacceptable to Albrektsson and Sennerby in 1991, and similarly unacceptable to the wider dental community today. The authors further maintained that latter data suggesting 85% success rate after 5-year follow up for intra-foraminal mandibular fixtures [15,16] seemed stringent enough for contemporary tastes.

A systematic review of success criteria in implant dentistry[17] charted the progression of implant success criteria from earlier authors[15,16] and demonstrated the evolution to contemporary thinking as it pertains to modern implants. The

paper lists factors such as survival rates; continuous prosthesis stability; radiographic bone loss; and absence of infection in the peri-implant soft tissues as being accepted parameters for establishing implant success. The principle argument of Papaspyridakos and colleagues however, is that new parameters had been introduced that provide additional information to complement the previous definitions of implant success.

These newer parameters point to the various aspects of achieving a life-like implant restoration, including: health status and natural appearance of periimplant soft tissues; prosthodontic parameters; aesthetics and patient satisfaction [18-21]. It was papers such as these that captured the evolving mindset of implant success and its increasing complexity. Papaspyridakos maintains that while osseointegration continues to remain the "predominant parameter" in implant-dentistry, the wider gamut of reported parameters should certainly be included in any comprehensive definition of the term.

His systematic review looked at 25 publications (2 randomised control trials and 23 prospective studies) for its analysis[22]. The authors of the review deemed that only two of the 25 papers had a low risk of bias, with the remaining carrying a medium risk. A variety of implant restorations were spread across the publications too, with seven papers on implant overdentures, 12 papers on implant fixed partial dentures and 14 papers detailing single implant crowns.

As each of the 25 papers deal with implant success in their own way, they each use their own criteria. The four most frequently used parameters were related to implant fixtures, periimplant soft tissue, prosthesis, and patient's subjective evaluation. There are a number of factors observed at each of the four success criteria as follows:

Implant Level:	pain; bone loss during first year <1.5mm; annual bone loss <0.2mm thereafter; radiolucency; mobility; infection
Periimplant soft tissue:	probing depth >3mm; suppuration; bleeding; swelling; plaque index; width of keratinized mucosa >1.5mm; recession
Prosthetic Level:	minor complications (chairside repair); major complications/failures; aesthetics; functional
Patient satisfaction:	discomfort/paraesthesia; satisfaction with appearance; ability to chew; ability to taste; general satisfaction

As mentioned in Papaspyridajos' systematic review, it would seem inaccurate to assess several of these described outcomes separately, when the implant-prosthetic complex as a whole is necessary for a successful oral rehabilitation[22].

It is interesting to compare the differences however between implant survival and success rates with these widened criteria. Galucci and colleagues did just that, by comparing success criteria for implant-supported fixed complete dental prostheses that were based on the previously described parameters: implant; periimplant tissues; prosthodontics; and subjective criteria[4]. This paper looked at both survival and success rates of 237 implants placed in 45 edentulous patients undertaking fixed hybrid prostheses.

Following a delayed restoration protocol, patients received four to six implants that were left non-submerged and allowed to heal for three months. After healing patients received screw-retained fixed hybrid prostheses with distal cantilevers: these were mostly acrylic/titanium hybrids, although four patients did receive ceramo-metal constructions.

Galucci and colleagues reported a 100% implant survival rate over 5 years compared with a 95.5% prosthesis survival rate. Interestingly, by contrast, the overall treatment success rate was comparatively lower at 86.7% with 6 out 45 patients not meeting the minimum criteria for success: of these six, two patients required replacement of the entire prosthesis while the remaining four patients presented with greater than four complication events.

There were a total of 79 complication events in the study, with the paper dividing these events into biological and technical categories. Biological events numbered 25 out of 79 and thus attributed to 31.6% of the total number of complications, of

which comprised: change in medical condition; reversible numbness of mental nerve; TMJ pain; inflammation around an implant; inflammation under prosthesis; bone loss around an implant; ulcer(s); hypertrophy or hyperplasia of tissue; cheek biting; swelling of soft tissue; soft tissue healing; hard tissue healing; and implant components.

By comparison, technical complications accounted for 68.4% (n=54/79) of all complication events and where thus more frequently encountered over the five-year follow-up period. These 54 numbered events are able to be further sub-divided into implant-related (n=8; healing screw; final screw loosening; and final screw fracture) and prosthodontic-related (n=46; fracture of acrylic tooth or denture base; fracture of porcelain; fracture upper denture; inflammation under maxillary prosthesis; fracture metal framework; composite access plug; improper relationship of maxillary and mandibular prosthesis; patient unhappy with aesthetics, requiring lab remake; and abutment framework damage when polishing)

It is interesting to note the results presented in Pjetursson and colleagues' systematic review of 2007 demonstrated implant/prosthesis survival rates over 95% at five years (Implant supported single crowns 95.5%; Implant supported fixed dental prostheses 96.8%)[23] and almost 90% at 10 years (Implant supported single crowns 89.4%; Implant supported fixed dental prostheses 86.7%). However in a similar fashion to the Galluci paper[4], Pjetursson reported a high complication rate of 38.7% of patients with implant-supported fixed dental prostheses over 5

years. Importantly, this figure is based upon a review of four papers only[24-27], totaling 266 patients that encountered a total of 122 complications during the observation periods. It's worth noting that this could be considered relatively few papers to elucidate complications data from, however it is a similar patient number to the Galluci paper of 2009, detailing 5-year survival/success criteria. The most frequent complications cited were technical in nature; with fracture of veneer material (ceramic fracture or chipping), abutment or screw loosening and loss of retention being the most commonly encountered technical complications.

If gold-resin reconstructions were to be excluded from the analysis, focusing solely on ceramic fractures/chippings for ceramo-metal reconstructions, the 5-year complication rate drops from 11.9% to 8.8% for implant-supported fixed dental prostheses and from 4.5% to 3.5 % for implant-supported single crowns[23].

Abutment or screw loosening demonstrated a 5-year complication rate of 5.6% for implant-supported fixed dental prostheses and 12.7% for implant-supported single crowns. The results for implant-supported single crowns are improved through the removal of an outlier study[28] by Henry and colleagues that focused on the first generation of single crowns in Brånemark implants. Exclusion of this study and its 107 Brånemark implants, reduces the cumulative incidence of screw loosening from 12.7% to 5.8%

The third most common technical complication was the loss of retention, or fracturing of the luting cement in cement-retained prostheses. Of the 753 fixed

dental prostheses analysed, loss of retention occurred in 45 of them. The five-year loss of retention rates for implant-supported fixed dental prostheses were 5.7% and 5.5% for implant-supported single crowns. Two papers by Brägger and colleagues[25,29], reported on the same cohort at both five and ten year intervals, presenting the cumulative incidence for loss of retention as 2.9% at 5 years, but markedly increasing to 16% after 10 years.

Salvi and Bragger[30] examined the mechanical and technical risks that are encountered in implant therapy. Through their appraisal of the literature, they examined 10 mechanical risk factors from a selected group of 35 articles: type of retentive elements supporting overdentures; cantilever extension(s) on fixed dental prostheses (FDPs); cemented versus screw-retained FDPs; angled/angulated abutments; bruxism; crown-to-implant ratio; length of the suprastructure; prosthetic materials; number of implants supporting an FDP and history of mechanical/technical complications.

Consideration of the mechanical aspects that contribute to the overall result is an issue therefore that was considered in preparation for this study, and while it is not our aim to establish an objective criterion for the mechanical characteristics of implant prostheses, certainly evaluation of the respective componentry and their interactions contributes to the discussion of how mechanical characteristics are symbiotic with the biological, surgical and artistic aspects of implant therapy's success and survival.

As far as further technical complications with respect to implant-supported fixed dental prostheses and implant-supported single crowns, Pjetursson and colleagues found component fracture (implants, abutments and occlusal screws) to be a relatively rare complication, occurring for only 21 abutments and occlusal screws out of a possible 3611 implants contained in the review. This translated into a five-year abutment/occlusal screw fracture rate of 1.5% for implant-supported fixed dental prostheses and 0.35% for implant-supported single crowns.

Of note, the authors of this review drew some conclusions as far as research implications for survival and success of implant therapy in addition to their commentary on biological and technical complications. Pjetursson and colleagues felt that the literature heterogeneity on survival could be overcome if future authors reported data on survival in combination with complication incidence, as was detailed in the review itself.

The paper goes on to suggest that biological complications be defined by: the threshold level of pocket probing depth (PPD); the presence/absence of bleeding on probing (BOP)/suppuration assessed at any examination interval; and crestal bone loss over time should be described for implants and neighboring teeth.

Similarly, the paper proposes that technical complications enjoy set criteria also, dividing these into: major (implant facture, loss of suprastructures); or medium (abutment fracture, veneer or framework fractures, aesthetic and phonetic complications; or minor (abutment and screw loosening, loss of retention, loss of

screw hole sealing, veneer chipping and occlusal adjustments). They additionally underline the importance of recording the type and number of technical events as well as the time and cost that go into rectifying the issues.

In spite of the few papers (four) included in the part of Pjetursson's review outlining complication rates of both implant supported fixed dental prostheses and implant-supported single crowns, it is prudent to acknowledge the strict inclusion criteria utilised for the review. With such a vast array of potential complications, strict criteria are needed to have an accurate measurement of success as even relatively small complications with implant-retained prostheses could lead to a restoration being deemed unsuccessful, leading to a potentially inaccurate outcome for research purposes.

It is important that clinicians have this understanding and an evidence-based trust of clinical implant therapy, which is based upon decades of research and experimental methodology. This then permits an additional methodology for replacement of teeth outside of tooth and tissue supported (or retained) treatment modalities of fixed and removable dental prostheses.

2.3 Timing of Implant Failures

In spite of implant therapy being a predictable treatment modality for tooth replacement[5-7], it is inevitable that implant failures will still occur. Chronologically, the timing of these events are classified as either early or late failures.

Snauwaert and colleagues looked to differentiate failures across these lines once the restoration had been completed[31], examining 4971 Brånemark implants across 1315 patients for time-dependent failure in a retrospective study. The observation period spanned 15 years, with a mean of 5.1 years. In this study, early failures are dually described as those occurring during healing time and/or those that occur within the first year after abutment connection (inadequacy of the host tissue to establish), whereas late failures are described as those occurring one year or more following abutment connection (failing to maintain osseointegration).

An implant was considered a failure if:

1. An individual, unattached implant was visually mobile or revealed a Periotest Value $\geq$ +8
2. A radiograph did demonstrate any evidence of periimplant radiolucency
3. An implant caused pain, infection, or paraesthesia
4. An implant fractured
5. An implant wasn't used for the retention or support of the prosthesis, because of its malposition (iatrogenic failure)

Amongst the patients (n=1315), the cohort was split into compromised patients (n=59) and non-compromised patients (n=1256), with the compromised patients defined as those required grafting with autologous bone and/or patients having undergone irradiation of the head/neck area.

There were four prostheses used in the study, described as such: single tooth replacement, fixed partial and full prostheses and overdentures. There was a relatively equal spread across maxillary (n=717) and mandibular (n=757) arches. Recall was set at 6-12 monthly following abutment installation, with standardized radiographs taken at 1, 2, 3 and 5 years. After 5 years, radiographs were taken every 3 years. Additionally, the rigidity of the bone-implant connection was assessed from 1998 onwards using the Periotest. This instrument provides a quantitative score that can assist in determining the extent of bone-implant contact and thus contributing to an assessment of the overall health of the implant. Periotest values were obtained at abutment installation, prosthesis installation, and upon discovery of radiolucencies about the fixture. There was also a test conducted if pain or inflammation was observed after prosthesis removal.

Of the two patient cohorts, compromised (n=59) and non-compromised (n=1256), a failure occurred for 24 (40.6%) and 146 (11.6%) patients respectively. At an implant level, there were 4661 implants installed in non-compromised patients, with 287 of these failing (6.1%); Of the 310 implants installed for compromised patients, 59 of these failed (19%). As described previously, reasons for failure were either biological, mechanical, or in this paper, iatrogenic.

Early implant failures (those occurring during healing or within the first year) were found in 3.4% of non-compromised patients and 12.5% of compromised patients respectively; late implant failures (those occurring one year or more following abutment connection) were at 2% and 7.4% respectively. Early and late

failures were more frequently encountered in the maxilla over the mandible. Additionally, implant length seemed to play a part in the cohort, with higher failure rates found to be higher for 7mm implants (21.5%) compared to 13mm (4.1%) and 15mm (3.8%) fixtures.

In a 2002 retrospective cohort study by Vehemente and colleagues[32], the authors evaluated the 1- and 5-year survival of Bicon dental implants in addition to identifying the risk factors associated with implant failure. During the study interval (May 1992 – July 2000) there were 702 patients treated. Of these, 25 patients were unavailable to follow-up being either deceased or otherwise. Therefore the study comprised 677 patients with 2349 implants that were placed by practitioners with varying degrees of clinical implant experience at the Implant Dentistry Centre (Faulkner Hospital, Boston, Massachusetts). In an attempt at statistical validity, one implant was randomly selected from each patient, resulting in a final implants sample size of 677 implants.

The Bicon dental implant is a unique design that utilises a 1.5° internal locking taper that acts to retain the abutment/crown complex without the need for abutment screws, instead using reduced tolerances between opposing surfaces to retain the prosthesis. The company's promotional material refers to this as an Integrated Abutment Crown or an IAC™ (www.bicon.com).

In addressing the papers objective of implant-failure risk factors, the authors grouped predictor variables into the following categories: demographic; health

status; anatomic; implant fixture-specific; prosthetic; perioperative; and ancillary variables. The major outcome variable was implant failure, defined as implant removal. From a statistical analysis perspective, implant survival was estimated using Kaplan-Meier analysis and risk factors were identified via Cox proportional hazards modelling. In terms of the type and number prostheses analysed in this study (n=677), there were six hundred and thirty-two fixtures restored as fixed single crowns or fixed dental prostheses (single implant crowns and bridges, n=632), whereas forty-five were utilised as some type of abutment for a removable prosthesis (removable, n=45).

Vehemente and colleagues reported on their two specific study aims. Their primary aim of implant survival rate: 1-year and 5-year survival estimates reported at 95.2% (95% Confidence Interval: 93.5-97.0%) and 90.2% (95% Confidence Interval: 86.0-94.4%) respectively.

Their secondary aim of identifying risk factors for implant failures arrived at two statistically significant results, finding both tobacco use (P=0.0004) and single-stage implant surgeries (P=0.01) as risk factors for implant failures. Through the Cox proportional hazards model, tobacco use had a hazard ratio of 4.3 (95% CI: 1.9-9.7, P=0.0004), indicating that smokers had a 4.3 times increased risk of implant failure versus non-smokers. Similarly, the hazard ratio for single-stage implants versus two-stage implant surgeries was 3.0 (95% CI: 1.3-6.9, P=0.01), indicating that there was a 3.0 times increased risk of implant failure for single-stage implant surgeries compared with two-stage surgeries.

The authors made the interesting comment that of all the risk factors assessed in their study[32], the two statistically significant factors associated with failures were under some form of clinical control, allowing a clinician to essentially moderate and optimise a clinical outcome to the best of their ability, ie- a clinician can choose to place implants in smokers or non-smokers or equally choose to use single or two-stage implant placement protocols.

The results of this study compare to other similar studies regarding implant failure risk factors[33,34], which detail factors such as implant surface roughness, smoking and history of periodontal disease. When retrospectively analysing 907 Brånemark System Mk III TiUnie/Groovy implants, Hasegawa and colleagues considered similar risk factors in their evaluation of implant failures. These factors included: age, sex, smoking habit, general health, history of radiation therapy, application of a dento-maxillary prosthesis, type of prosthesis, use of alveolar bone augmentation, site of implant insertion, mechanical coupling (or splinting) between implants, and the length and diameter of the implants themselves[35]. Of the 907 fixtures, there were 23 failures with an overall survival rate of 96.7%.

Implant success in this paper was defined as per the Buser protocol of 1990[36] whereby patients success was defined as: (1) absence of persistent subjective complaints such as pain, foreign body sensation, and/or dysaesthesia; (2) absence of periimplant infection with suppuration or mobility; and (3) absence of a

continuous radiolucency around the implant. Interestingly, over and above this classification, Hasegawa and colleagues decided to classify an implant as surviving, but not successful if it had been previously associated with a history of acute infection with suppuration and progressive bone loss.

Statistical univariate analysis showed significance ($P<0.05$) for the following implant failure risk factors: increased age, history of radiotherapy, application of a removable prosthesis or a dentomaxillary prosthesis, lack of mechanical coupling between implants, and shorter implants (≤ 8.5mm). The authors conducting further multivariate analysis and identified significant association ($P<0.05$) between implant failure and whether or not there was mechanical coupling (or splinting) between implants. Implants that were not splinted had an odds ratio of 6.88, indicating that they were 6.88 times more likely to fail in this study. As part of the same multivariate analysis, there was a significant association ($P<0.05$) between implant failure and shorter implants (≤ 8.5mm), with an odds-ratio of 3.43, or 3.43 times increased of implant failure if the implant length was ≤ 8.5mm. This is similar to results presented by Snauwaert and colleagues regarding the 7mm implants evaluated in their study, comprising 21.5% of total implants failures verses both the 13mm and 15mm fixtures (4.1% and 3.8% respectively)[37].

It is interesting to note demographic factors such as sex ($P=0.295$); smoking ($P=0.16$); diabetes mellitus (0.156); steroid treatment (0.207) and osteoporosis ($P=0.518$) were not found to be significant risk factors for implant failure by Hasegawa and colleagues. Similarly, clinical risk factors such as bone

augmentation (P=1.000), anterior/posterior implants (P=1.000), maxilla/mandible implants (P=1.000), type of edentulism – complete or partial (P=0.125), or implant diameter (0.762) were all found to be not significant risk factors for implant failure[35].

The timing of dental implant failure is also something considered by Sahin and colleagues. The authors described late implant failures as being predominantly related to biomechanical complications. As the connection between an osseointegrated implant and fixed superstructure is rigid, a strain is induced upon each component that is exposed to any incidental force. The superimposition of functional loads generates additional strains that affect the entire bone-implant-prosthesis assembly[38]. It is therefore the challenge of the restorative clinician, to deliver a prosthesis that is acceptable of, and considerate to, the rigid connection between implant and abutment/restoration that does not compromise an optimal outcome and the longevity of the treatment.

Sahin's paper examines the concept of framework misfit in detail during its discussion on biomechanical complications. While the author posits that "passive fit" is assumed to be one of the most significant prerequisites for the maintenance of the bone-implant interface, he concedes that the scientific evidence is lacking, going as far as saying that absolute passive fit cannot be obtained[39]. While there are a number of prosthetic complications that may arise, Sones describes her list as a potpourri of complications[40], including: gold (fixation) screw loosening or fracture; abutment screw fracture; veneering material fracture; prosthesis fracture,

misfit of gold cylinders, frameworks and veneers have all been related to poor framework fit. However Sahin acknowledges that there are no longitudinal clinical studies reporting implant failure specifically attributed to framework misfit.

Taylor and colleagues expand on this idea further, maintaining that the mechanism and relationship between biomechanical complications and implant failure is poorly understood[41]. Taylor proposed two questions that required investigation in order to truly determine the relationship between the misfit of componentry and its impact on the surgical/prosthetic unit.

> "First, what level of misfit is clinically important, beyond which damage is likely to occur?"

Intuitively, Taylor answers his own question with the following response:

> *"The answer to this question is obviously very complex and probably depends upon such factors as bone quality, length and diameter of implants, and implant surface characteristics.*

His second question speaks to the empirical and/or clinical assessment of said misfit:

> *"Secondly, assuming that misfit is a concern, how does one measure it in a clinical situation?"*

The impact of these statements is that it clearly identifies a perceived problem within the clinical aspects of implant therapy that challenges the current level of available evidence. The importance of the issue is underlined later in the paper as being an area of high-priority research, where he proposes that if misfit is a risk-factor for implant failure, then clinicians are in need of a tool to measure said misfit and to ultimately avoid its occurrence at potentially damaging levels of magnitude. Further, if a moderate level of misfit (undefined in the paper) turns out to not be a significant risk factor for implant failure, then there becomes a decreasing need for technology to provide continuously more precise, and therefore expensive, implant superstructures.

In the contemporary dental world, there has been an explosion of technologies in the digital sphere that aim to achieve this very thing, the ideal prosthesis, with complete passivity of fit. However, as Taylor described in his 2000 paper, there is no evidence to suggest that such high levels of precision are necessary for long-term implant bone health, rather there is a need for improved understanding of the short, medium and long term affects of misfit on the stability of the bone adjacent to dental implants at each time period.

Despite the lack of longitudinal data on the biologic outcomes of prosthesis misfit, there is the assumption of an increased incidence of mechanical complications (prosthesis misfit, screw distortion, screw loosening, component fracture, implant fracture/failure) that may arise or increase in the presence of componentry

misfit[23,41,42]. Mechanical stability can only be ensured if complementary componentry actually fits, therefore there would seem to be a logical and justified need for accurate and passively fitting restorative components. This will be covered in further detail later.

2.4 Assessment of significance of componentry misfit

While conceding that an acceptable marginal fit of a restoration does not equal passive fit, Taylor and colleagues describe a theoretical *in vivo* methodology for assessing misfit between implant componentry as a springboard for quantification of misfit magnitude, something that was also touched on by other authors[43]. This may then be used to correlate with any potential adverse biologic host response. Determining the degree of superstructure passivity would rely on an analysis of strain as it applied to each implant abutment and/or component of the prosthesis before and/or after fixation (screw or cementation).

A procedure that is able to capture this level of detail would ultimately require the attachment of strain gauges to individual areas of interest within/on the implant/prosthetic complex. The authors propose that this would be expensive, time consuming and ultimately impractical for inclusion in a routine treatment protocol[38]. Empirically though, having access to the necessary equipment may provide some interesting data, however extrapolation of said data to the individual clinical situation present at a singular prosthetic connection may prove difficult.

Expanding upon previous comments regarding mechanical stability and passivity of fit, it stands to reason that marginal gaps between frameworks or restorative componentry and implants, if excessive, may prove problematic. While the literature demonstrates that tooth-borne restorative marginal gaps can vary widely[44-48] and remain clinically successful, the implant literature is unclear with respect to the consequences of biological sequelae regarding implant-borne marginal gaps. Sahin and colleagues concluded however that when sufficiently large gaps exist between componentry, then a large external preload is introduced onto the implant abutment and/or fixation screw, possibly leading to screw loosening and/or fracture[43,49-54].

Sahin explains a mechanism for screw loosening: whereby insufficient counteracting torque is present to oppose the bending of an ill-fitting framework when connected to an implant abutment. This effectively leads to creation of a lever arm at some point within the connection, overloading all components of the affected implant[38,55]. In situations where fixation screw loosening doesn't occur, internal stresses may increase to such a point that fracture of framework may occur if it has not been designed to be sufficiently robust; in cases where frameworks are spared, the increased forces are transferred to abutments or implants, potentially having interactions with implant-bone interface.

In a 2014 systematic review, Abduo noted that while framework misfit may alter the biomechanical situation at an implant/abutment interface, there is insufficient evidence available to confirm that this induces a negative biomechanical outcome.

Additionally, from a biological perspective, there is a deficiency in the literature with respect to high order prospective human studies to support the concept of periimplant bone resorption as a result of framework misfit. In general terms occlusal forces are imparted upon oral implants and the surrounding bone. When the implant is loaded, the stress will transferred to the bone, with the highest stress in the most coronal portion of the supporting bone. This concept is related to a general engineering principle that states when two materials are in contact, in this situation bone and titanium alloy, then the stress will be highest where the materials make their first contact[56]. However, Abduo did agree that inherent stresses within the associated componentry increase proportionally with componentry misfit, as does the instability of the connection, conceding that once again, the clinical significance of this is yet to be determined[57]. To take this concept a step further, with bone being strongest under compressive load, weaker under tensile load and weaker still when undergoing shear forces[56], it stands to reason that any load other than axial and therefore compressive may have an adverse outcome for the associated periimplant bone.

Unfortunately the majority of evidence in this area is supported by animal studies and FEA studies. It can be assumed that a poorly fitting prosthesis or framework may lead to a non-axial load being applied to the implant system. Barbier and Schepers considered the influence of axial versus nonaxial force loading upon the concept of bone remodelling about implants, in dogs[58]. They found that under axial load, a more uniform and consistent bone remodelling response occurred that would gradually dissipate moving from the initial crestal zone to the

implant's apex. In contrast, nonaxial loading created a more dynamic remodelling. Cortical bone was affected, to a greater degree than axial loading, however as the histological sections moved apically, a wider derangement was noted in the trabecular bone. With respect to digital modelling, authors have utilised three-dimensional finite element analysis to produce dynamic mock-ups of the periimplant bone under loads both axial and non-axial, finding that non-axial loads present more of an issue to the adjacent crestal bone than axial loads[59]

An interesting *in vitro* study by Jemt[60] considered the distortion in three dimensions (x, y and z planes) for cast gold-alloy full arch prostheses in the maxilla and the mandible. Assessment of the relative positions in space was compared between master models and intra-orally and recorded using a photogrammetric technique. While the results of the study indicated increased distortion between master models and intra-oral sites occurred when jaws were wider and more curved, ranging between 11μm and 181μm in the mandible and 133μm and 315μm in the maxilla. It was also noted that implant alignment and casting size played a role in the results, with sagittal distortion (y-axis) being the most significant vector of distortion noted. As part of the study, Jemt adapted one of his earlier protocols from 1991 that explained his assessment for prosthesis fit utilising the dimensions of abutment screws, a test that became know as the Screw Resistance Test.

The abutment screws used at the time were Nobel Biocare gold alloy, with a known distance between screw threads of 300μm. The authors would apply

preload to the abutments screw, tightening down to the point of first resistance. At this point, the clinician would then tighten the screw no more than half a turn further/180° equating to a vertical distance of 150μm or half the distance between the abutment screw threads. A constant torque of 10-15Ncm^{-1} was used throughout. If more than 180° of turn was required during the transition from 10Ncm^{-1} to 15Ncm^{-1}, it was suspected that there was excessive misfit at some point and the prosthesis was altered or re-fabricated[60]. The authors suspected that the effect of marginal discrepancy is worse when the clinical gap is about this 150μm level.

Depending on the materials used in the prosthesis, the act of tightening screws is able to elicit a strain of varying magnitude in and around the dental implant itself. By inference, the magnitude of this is dependent upon the degree of misfit between the framework and abutment surfaces[43,61]. When an abutment screw is tightened, it has been shown that there is a distortion of both prosthesis framework and the implant proper. The framework misfits demonstrated by Kallus and Bessing[54] and seen to cause screw loosening were likely due to gaps greater in magnitude than the 30μm microgap recommended by Klineberg and Murray[62,63] and yet, 30μm is below such a level that it becomes difficult to discern clinically. Brånemark had actually stated previously that the precision of prosthesis fit should be at the 10μm level, this was to ensure what he termed "the adequate remodelling stimulus"[9,64]. So, with the distortion of metallic surfaces made by possible by the preload applied to them, a microgap of several hundred microns may in turn be reduced to such a point that it too is indiscernible

clinically, say with an explorer probe. This was demonstrated by Clelland[61] who proposed that even a microgap approaching 500μm may be undetectable given the distortion that is possible with a preload of $10Ncm^{-1}$.

Millington reported a different result however, finding that for microgaps greater than 55μm, the gold screw did not possess sufficient force to bend the superstructure enough to close the joint[65]. This was an interesting paper as it considered microgaps at implant abutment interfaces at different positions along a framework. Implants were fixed in a straight line, with superstructure geometry "kept simple, while maintaining a mass and stiffness akin to the clinical situation". The authors did admit however that designing curve-shaped superstructure on a curved test model would have better reproduced a clinical situation. Stress levels were assessed in the areas adjacent to the connection, when a vertical fit discrepancy is present, as was the case in Millington's experiment, the preload is used to bring opposing surfaces closer together. The act of doing this, attempting to overcome improper fit, makes the screw vulnerable to fatigue fractures and loosening. On the other hand, horizontal and angular discrepancies may result in the binding of the screws and induction of various bending stresses within the implant components.

Millington posits that precise torque and angulation control are needed, with the absence of either factor posing problems in situations where abutment screws are tightened in an attempt at gap closure. Results demonstrated stress induction on cast superstructures with fit discrepancies as small as 6μm.

When comparing the location of fit discrepancy, Millington found that when it was located at the end abutment, surface stress continued to rise with increasing discrepancy up to the largest gap size tested of 104μm. When the discrepancy was located at the intermediate abutment, the maximum rate of increase in stress occurred within 40μm, earlier than end abutment results. As mentioned previously, screw joints were unable to be closed when discrepancy reached a level of 55μm. Interestingly, stress magnitudes were higher when the fit discrepancy was located at an intermediate abutment compared with similar-sized discrepancies located at end abutments. Additionally, maximum surface stress on the superstructure was always found to be above the intermediate abutment, irrespective of whether the fit discrepancy was located at the end or intermediate abutments.

While the maximum stresses where always located above the intermediate abutment, the *type* of stress differed however depending on the discrepancy location: results demonstrated compressive stresses occurred when discrepancies where located at the intermediate abutment, whereas tensile stresses occurred when with discrepancies at end abutments[65].

Once again however, the biological ramifications of the misfit are questioned. The range of misfit demonstrated in the Kallus and Bessing study, across 283 implants in 50 patients, did eventuate in screw loosening, however there was no evidence in that study to show correlation with biological sequelae such as marginal bone

loss or loss of osseointegration. It must be noted however that type of abutment screw used in the study was a gold alloy screw. An explanation was suggested by the authors for gold screw loosening and is as follows:

> *"One possible explanation for gold screw loosening is that bone will remodel while releasing the pretension in the screw joint at the same rate as the tension and overload in bone diminish, thus leading to loosening of the gold screw over time. Another possible explanation is that because of the reduced clamping force, movements in the screw joints will occur, leading to loosening or settling. Since abutment screws are essentially stable, loosening would not seem to be a function of high loads, but rather related to framework misfit."*[54]

Prospective studies that intentionally place ill-fitting prostheses in humans are not readily available, likely due to ethical concerns. A small prospective study involving primates by Carr does attempt to bridge the gap in the literature however through evaluation of biological responses to ill-fitting prostheses[64]. In the study, six female baboons had two fixtures placed in the posterior mandible. Following delayed healing, the tapered abutments were placed. One abutment acted as the control, rigidly connected with a prosthesis that exhibited a good fitting relationship (with a mean linear distortion of 38μm across five specimens as one implant failed prior to abutment connection) with the other abutment acting as the test abutment, rigidly connected with a prosthesis that exhibited a poor fitting relationship (demonstrating a mean linear distortion of 345μm across six

specimens). Specimens within the study did not mimic the complete clinical situation however, as there was no dynamic load involved, instead it was an attempt to challenge the dogma of Brånemark's principle of misfit being within the 10μm limit.

The study sought to answer the clinical concern that poorly fitting prostheses impart a mechanical overload to the supporting bone, causing a reduction in crestal bone support. Within the limitations of this small sample size (and the animal model), the results suggest that the mechanical environment created by the two experimental groups, did not cause a difference in bony response. There was no significant difference demonstrated between the two groups, instead the bone response was contrary to the clinical expectations of the study authors[64], finding no difference due to prosthesis fit. Seeing a trend in their results, the authors felt there was little ethical justification in sacrificing further primates to improve the statistical power of their result, however conceded that further biomechanical research was needed in this area of implantology.

Expanding upon the ability of clinicians to check for misfit intra-orally, one is reliant upon keen eyesight, adequate lighting, magnification, angle of vision and background/level of clinical experience. There can be a wide range in the ability of a clinician to discriminate various levels of misfit. The Jemt protocol has been described previously, whereby a half turn of the abutment screw at a preload of $15Ncm^{-1}$ is all that is permitted once initial resistance has been met, thus ensuring ideal fit that is less than the half distance between screw threads - 150μm. The

variation amongst the literature in regards to detectability of distances less than 150μm is established, with publications demonstrating microgaps amongst the implant and tooth borne prostheses literature[61].

In Abduo's review paper of 2010[66], he tabulates data outlining clinical and in vitro methods for assessment of framework misfit. Both advantages and disadvantages are outlined, as well as a subjective viewpoint regarding degree of accuracy.

The use of tactile feedback, or "*Tactile Sensation*" as described by Abduo, is a technique that every clinician uses during virtually every clinical procedure in dentistry. Its use was described by Hayashi and colleagues as being a superior technique to simple visual inspection (both with and without dental loupes) when detecting marginal discrepancies[67]. An additional Hayashi paper in the same year considered the concept of both vertical and horizontal discrepancies and the use of explorer tips of various sizes being able to detect them[68]. In the study, Hayashi created three experimental devices, one that simulated vertical steps, one for horizontal steps and another that created a combination of the two. The gap distance that was created in each of these devices began at 0μm and increased at 2μm per millimeter up to a maximum gap of 270μm. The study used dental explorers of five different tip diameters—120, 170, 220, 350 and 500μm, each confirmed by means of a scanning electron microscope. It has been show in other studies that a new explorer tip diameter can range between 60 and 120μm[68,69], so

the five different tip diameters were representative of both new and perhaps used explorer probe tip diameters.

The study found that for the given instruments used, explorer tip diameter had no significant effect on the detection of vertical step discrepancies, however did demonstrate a significant effect when it came to detection of horizontal gaps. All explorer probes used in the study were able to detect discrepancies smaller than 170μm. The authors questioned the need for explorer probes with a tip diameter less than 500μm in clinical studies, as there may be a tendency to inappropriately record gaps between surfaces and recommended for prosthetic replacement. Whereas, these false positive gaps could be of the type that represent no associated with risk of relatively early failure; rather it may be more indicative of a less than ideal marginal adaption.

Dedmon published on the question of disparity between clinicians and what they found to be clinically acceptable, finding wide variations amongst clinicians. Within that study, clinicians considered horizontal marginal openings between 32μm and 230μm and vertical openings between 43μm and 196μm clinically acceptable[70]. Tactile and/or visual inspection alone is likely to be insufficient in accurately determining framework misfit due to high subjectivity, particularly in cases of subgingival margins. While there can be wide variability amongst clinicians in their ability to detect misfit using these methodologies, it is an important tool that to be used in conjunction with other more accurate approaches[69].

The use of radiographs to detect and evaluate misfit has been reported previously[71]. As described before, subgingival margins are more challenging for clinical detection. Through addition of a periapical radiograph, one may be able to confirm a suspected gap discovered through tactile sensation with an explorer probe. This becomes particularly evident when films are taken as perpendicular to the fixture-abutment connection as possible, thus optimising the quality and precision of the image. This aids in reducing overlapping of the abutment and implant that may artificially obscure any existing gap, thus preventing superimposition and false positives[66,69]. Cameron[72] and colleagues considered the clinical situation carefully, devising a study whereby a range of angulations deviating away from 0°, or perpendicular, were used to assess the diagnostic status of the radiograph to a trained observer when evaluating the implant-abutment connection. The authors reported upon angle variations at 5° increments from 0° to 45°, finding that a periapical film was diagnostic for correct implant-abutment seating when the tube head is maintained at less then 20° from perpendicular to the long axis of the implant. Importantly, this number is regardless of the angulation that has been given to the film.

The Sheffield Test, occasionally referred to as the "One Screw Test", is a simple assessment of fit that can be applied to long span frameworks. It was first described by Jemt[73] and then later expanded upon by Tan[51]. The technique involves seating of a framework onto the abutments and tightening a single terminal abutment screw. Clinicians then observe and assess the remaining

abutments that have not been screwed down, looking for gaps that may suggest misfit. Often the opposite terminal abutment will show the most marked variation in misfit if an error has occurred due to a larger radius of arc[51,69]. There is the potential for false negatives with this technique however in the case of a so-called "bottoming-out" phenomenon. If discrepancies have arisen in the negative z-axis direction, i.e.- downwards, then an abutment may move in this downward direction during tightening, preventing the other cylinders nearby from reaching their natural position. This would probably go undetected both on a laboratory master cast, as well as intraorally, leading to a distorted framework being assessed as a "well-fitting" casting[51].

Disclosing materials are useful tools that are often used in conjunction with the Sheffield Test described earlier. The types of materials available vary based upon clinical preference but may include wax, fit checker, pressure indicator pastes, even items of know thicknesses such as unwaxed dental floss (12μm), polyester trips (40μm) and shim stock (10-12μm). The presence of disclosing media present at the interface of implant-abutment connections may be a prime indicator of framework misfit[69]. This is similar to the discovery of plaque, calculus or debris being found between the mating surfaces of abutments and frameworks during removal of said frameworks from the mouth for maintenance purposes. This provides a clear indication that opposing surfaces haven't been completely seated, allowing ingress of various materials into the connection space[74]. Disclosing media are able to produce results whether supragingival or subgingival, however results tend to be more reliable in a supragingival setting.

Jemt's Screw Resistance Test has been described earlier and is listed as one of Abduo's clinical methods for assessment of framework fit in table 1. Kan makes an interesting point regarding this test however, stating that it can only be applied when Nobel Biocare gold prosthetic screws are utilised (throughout the literature, prosthetic screws have additionally been referred to as fixation screws, however the intention is to refer to screws that maintain the connection of a framework to an abutment. - abutment screws being those that attach abutments to an implant). These gold prosthetic screws possess a displacement between threads of 300µm. By contrast the displacement between screw threads for a Nobel Biocare abutment screw and its compatibles is 400µm. Other systems may have abutment screw thread displacements that vary from 300 to 350µm[69]. As such, the guide of "one-half turn of a prosthetic screw and/or 150µm" being an acceptable clinical guide that demonstrates a framework fit has the potential to be misleading. In addition, there are a wide variety of recommended torque values across multiple implant systems and implant hardware, ranging from $10Ncm^{-1}$ to $45Ncm^{-1}$. Kan correctly asks the question therefore as to whether the principles of the screw resistance test should be applied regardless of the implant system used.

To expand upon this idea further, if one were to know the correct displacement between the threads of a screw being used, the principle of the screw resistance test may be altered to suit the purpose. One might then be able to know the maximal vertical distance one half screw turn might produce, i.e.- a 400µm thread displacement would create a maximum 200µm distance through a half rotation of

the screw. However, knowing this distance does not give all the information, as it fails to take into account the influence of the preload applied to the system. The turning force per unit of distance described by Jemt is the moment between $10Ncm^{-1}$ and $15Ncm^{-1}$; for an abutment screw with a manufacturer-recommended torque of $35Ncm^{-1}$, one would assess this to be completely unsuitable clinically. Equally, the materials used may be different, particularly in contemporary prostheses, whereby gold prosthetic screws are increasingly less common due to cost and prosthetic complications[54], instead we are likely to encounter titanium alloy screws in a clinical setting. From a prosthesis design viewpoint, there may be additional variations. Predominantly the literature speaks about the framework/prosthesis-abutment-implant design that requires both a prosthetic screw (to attach the framework to the abutment) and an abutment screw (which may or may not be integrated into the abutment, that joins the abutment to the implant). In certain clinical situations however an intermediary abutment may not be necessary, with a decision being made to attach the prosthesis directly to the fixture. Certainly this is a common methodology for single implant prostheses, however it also a design that might be utilised for external-hex style implant fixtures that have favourable angulations. In such a situation, issues with the screw resistance test will again be encountered due to the difference in abutment screw geometry (thread displacements), differences in torque values (higher for abutment screws) and differences in materials of choice for both prosthetic frameworks and screws (various compared with the cast-gold alloy frameworks or gold screws used in the Jemt paper).

The final methodology mentioned by Abduo as being a clinical methodology of assessing framework fit is the three-dimensional photogrammetric technique. This process had been previously defined by Jemt[75] also, detailing a technically-difficult process that can measure misfit to within 10μm. It permits merging of data from photographic records into a stereo three-dimensional image that can be linked to a computer for further analysis. At the time of its report, this technique was quite laborious and certainly costly, therefore making it impractical for chairside clinical use.

The merits and limitations of each test are apparent, and clearly evident in the tabular format published by Abduo. One must consider a combination of several methods rather than a single one, which ultimately speaks to a clinicians clinical experience and ability to understand and curate the intimate relationship desired for successful connection of implant componentry.

As additionally described by Sahin[38] and Wee[76] in separate publications, there several techniques available to improve the final fit of implant frameworks, however they also demonstrated that a totally passive fitting framework was not possible. Broadly, the categorisation of their techniques falls into three categories and is an attempt at lessening the potential for complications:

1. Strict control of each step within the stages of prosthesis fabrication[77]
2. Application of additional procedures to improve fit
    a. Sectioning and soldering of cast frameworks
    b. Laser-welding of titanium

c. Spark erosion with electric discharge machine

d. Intraoral cementation of framework onto cylinders

3. Elimination of conventional crown and bridge methodologies and replace with CAD/CAM technologies[78]

Clinical Methods to Assess Framework Fit[66]

Technique	Advantages	Disadvantages	Accuracy
Finger Pressure	Simple Quick	Inaccurate for subgingival margins Difficult to interpret	+
Visual Inspection	Easy	Subjective Detects only gross misfit Unsuitable for subgingival margins	+
Radiographs	Easy Available for subgingival margins	Overlapping and superimposition Must be standardised	++
Tactile sensation	Easy Simple	Requires accurate explorer Dependent on manual dexterity and sensitivity	++
Sheffield Test	Efficient for long-span prostheses	Does not detect three-dimensional misfit Requires experience	++
Disclosing materials	Easy Available	Limited to supragingival margins	+++
Screw resistance test	Accurate	Subjective Requires extra instruments	++++
Three Dimensional photogrammetric	Accurate Predictable	Expensive Not readily available Difficult to use Requires experience	+++++

Table 1: Clinical methods for assessing implant framework misfit, table reproduced from Abduo and colleagues

As mentioned, there are few articles within the literature that examine the issue of in vitro evaluation methods for the fit of fixed implant prostheses. There are also fewer attempts made at evaluation of in vivo methods. Abduo[66] was unable to identify any comparisons between in vitro and in vivo techniques.

A discussion regarding in vitro methods will now follow, however it is important to note that all of these techniques are based upon the assumption of homogeneous rather than heterogeneous bone, with the additional assumption that an implant is 100% osseointegrated, which clinically is not always the case. Abduo proposes that there are two broad categories that make up in-vitro analysis approaches: modelling and dimensional measuring techniques. Modelling techniques are empirically based and intended for use in a research laboratory setting that essentially simulates the clinical situation. These techniques can then be used for assessing the effect that inaccuracy of prosthesis fit has upon the bone-implant complex. By contrast, dimensional measurement techniques are simply a methodology used in the laboratory to measure distances between prostheses and the implants they are attached to or within the componentry themselves.

The first modelling technique proposed by Abduo is Photoelastic stress analysis. It is based upon the ability of particular translucent materials, when stressed, to exhibit colour patterns known as isochromatic fringes that are able to be observed under polarised light. By having a clear chromatic indicator, it is possible to determine the precise location of varying stresses within, or around, a structure during fixation or loading. As mentioned previously however, it is reliant upon the assumption of a homogenous distribution of material, simulating bone that surrounds the implant. From a clinical perspective this is not always the case and certainly when there is a less than ideal bone to implant connection, or heterogeneous interface, there is a greater clinical concern regarding the stress

distribution within a structure[55]. The additional limitation of this technique is the difficulty in matching the mechanical properties of the translucent Photoelastic materials to those of living bone, potentially introducing inaccuracies into the experimental model that do not translate into clinical situations. Additionally, this modelling technique is capable of producing observational changes within the Photoelastic material under experimental conditions; therefore this is a qualitative test that is unable to produce a quantitative result on its own.

Strain gauge analysis (SGA) is the second in-vitro modelling technique described by Abduo. In contrast with Photoelastic stress analysis, Strain gauge analysis is able to efficiently provide a quantitative result for stress exerted within and around analysed structures. The methodology requires attachment of a detecting electrode in the form of fine wire. More commonly however, it is in the form of foil arranged in a grid pattern in order to maximise the quantity of metallic wire or foil subjected to strain in a parallel direction aligned with the grid pattern; this then increases the sensitivity of the analysis. To prevent distortion of the fine wires, the grid is bonded to a thin backing, known as a carrier and directly attached to the specimen of interest. As the test specimen experiences strain, it can be transferred directly to the strain gauge due to its closely adapted proximity to the specimen; measurement occurs through linear changes in electrical resistance across the grid.

A ‘gauge factor’ is the quantitative result produced during the analysis and is the base measurement of the strain gauges sensitivity to strain within the specimen.

Abduo makes the supported claim that several studies show SGA to be a more sensitive test than Photoelastic stress analysis, highlighting that various strain gauges have detected otherwise hidden inaccuracies within clinically acceptable frameworks. Given the small scale of the detecting electrodes, SGA is also able to be applied in vivo for research purposes, with the ability to bond the strain gauge itself to frameworks or dental abutments[66]. The predominant limitation with this form of analysis however is that values are generated more or less as a snapshot of surface strain at a specific point where the gauge is attached, making results entirely dependent upon selection of the point of attachment. Unfortunately, there is an inability to measure effectively at areas of high curvature, which generally is where stain is highest and of clinical interest. There is the added issue of strain gauges being sensitive to temperature, which certainly becomes a confounding factor for in vivo testing.

The third and final in vitro modelling technique proposed by Abduo is finite element analysis (FEA). It is a system used broadly throughout the dental literature, after initially being developed in the early 1960s to solve the structural problems encountered by the aerospace industry[79]. It has useful applications to the field of implant dentistry, with a variety of publications detailing the bone-implant interface, the implant-prosthesis connection and the multiple-implant prosthesis. A purely in vitro technique, FEA allows the researcher to predict stress distribution in various areas of interest, such as the contact areas of implants with cortical bone or conversely the area around the apex of the implant where it contacts the trabecular bone.

With such a complex interaction of mechanical components with the surrounding biological interface, obtaining a useful analytical solution is difficult. In the Geng review, a summary of the technical aspects of FEA is provided:

> *"FEA overcomes this by dividing the problem domain into a collection of much smaller and simpler domains (elements) in which the field variables can be interpolated with the use of shape functions. An overall approximated solution to the original problems is determined based upon variational principles. In other words, FEA is a method whereby, instead of seeking a solution function for the entire domain, one formulates the solution functions for each finite element and combines them properly to obtain the solution to the whole body. Because the components in a dental implant-bone system are extremely complex geometrically, FEA has been views as the most suitable tool for analysing them. A mesh is needed in FEA to divide the whole domain into elements. The process of creating the mesh, elements, their respective nodes, and defining boundary conditions is referred to as "discretization" of the problem domain."*

As discussed previously, in vitro techniques require certain assumptions to be able to characterise and simulate clinical situations; this is particularly evident in the case of FEA. Geng states that the principle difficulty in simulating the mechanical behavior of dental implants is the modelling of human bone tissue and its response to applied mechanical force. As a result, within the published literature

authors have been forced to devise major simplifications to the complexity of the implant-bone system, these include factors relating to:

1. detailed geometry of the bone and implant to be modeled
2. material properties
3. boundary conditions, and
4. the interface between bone and implant

Geometry in FEA:

Weinstein and colleagues first reported the technique in the dental literature in 1976, publishing an article entitled "Stress analysis of porous rooted dental implants". Since that time we have moved from 2-dimensional FEA studies to 3-dimensional and integrated this with more advanced digital imaging techniques to more accurately render anatomically accurate models, for example, there now exists software with the capability to directly transform two- or three-dimensional date from computed tomography (CT) or magnetic resonance imaging (MRI) into FEA meshes for analysis[79]. This allows for more precise geometry within the FEA simulation, however in the past there has been comparatively simplified attempts at modelling the geometry, with bone modeled as a simplified rectangular structure along with the implant, considerably simplifying the system and raising questions of clinical relevance with through such over-simplification.

Material properties in FEA:

In FEA, material properties significantly influence the stress and strain distribution within a defined structure and are defined as isotropic, transversely

isotropic, orthotropic and anisotropic. As the term suggests, within an isotropic materials, the properties are the same in all directions; an anisotropic material has different properties when measured in different directions; with many material constants present depending on the degree of anisotropy (transversely isotropic, orthotropic)[79].

Expanding on the description of homogeneous modelling assumptions described by Abduo, Geng maintains that most published FEA studies make the same assumption, having a linear and homogeneous predilection and an elastic material behavior characterised by two material constants of Young's modulus and Poisson's ratio. It is interesting and critical to note that most early studies ignored the trabecular nature of bone as there lacked a capacity to accurately determine the trabecular capacity. One of the greatest assumptions in these analyses therefore was that trabecular bone exhibited a solid pattern inside an inner cortical bone shell; subsequently the model exhibited the simplified overall view as being linear, homogeneous and isotropic. Once again, in Geng's review on FEA, it is pointed out that cortical bone has been shown to be neither homogeneous, nor isotropic, having it's own elastic properties and gradients both longitudinally and transversely.

Boundary conditions in FEA:

Boundary conditions are parameters used to help define the FEA model by setting a known value for a distance/displacement or an associated load. These conditions are commonly fixed in dental FEA models, however in situations where there is

variability of displacements or loads, such as a moving mandible, the model can prove inaccurate. Once again, Geng describes a recent study in which an FEA model was designed that utilised simulated cable elements to address the clinical action of muscles of mastication. This was then able to improve the overall model mimicry and accuracy to the clinical situation, rather than static, fixed boundary conditions.

Bone-Implant interface in FEA:

As previously described, most FEA models are conducted with the assumption there is an ideal level of osseointegration, with full bone-implant contact at a trabecular and cortical level. As this isn't a clinical reality, the software driving contemporary FEA modelling has been improved to allow a variety of 'contact algorithms' to feasibly simulate a more clinically accurate bone-implant interface.

Abduo rated FEA as the most accurate in vitro methodology in spite of all the assumptions required, particularly the sensitivity to the boundary conditions set by the investigator. He describes the technique as useful in analysing the fine detail of 'minor implant components, such as screws' and the ability to anticipate the biologic behavior of the periimplant structures subject to loading and framework fitting. Combining the three modelling techniques described by Abduo, rather than taking each in isolation, provides different but beneficial information for determining either the stress associated with the degree of misfit or to assess the effect of misfit[66]. Incidentally, combining photoelastic stress analysis and strain

gauge analysis was something that Brosh regarded as being complementary techniques, each providing different, but important information[80].

Abduo continues his list of in vitro methods for assessing framework fit with the dimensional techniques, the first of which being the microscope. The microscope is a common feature within the dental laboratory and are available in a range of magnifications. The ability to measure gaps between components, thickness of impression materials that may be filling the gap or a section of a sample is certainly advantageous. However, it is mandatory that a standardisation with reference points for any microscopic imaging be incorporated. It is recommended that digital photographs (or otherwise) be taken with a macro lens and then magnified afterwards. Within the photos field of view, a scale bar of known distance is used as a reference such that it can be scaled with any magnification of the photograph during the analysis[66]. The use of microscopy is a relatively straightforward and inexpensive technique that significantly requires comparatively little floor or bench space when compared to other techniques. The accuracy and precision of microscopy results is reliant on appropriate standardisation for repeatable analysis across more than one sample[81].

The second dimensional method has been mentioned earlier: photogrammetric technique. As an assessment tool in dentistry, it was first introduced by Lie and Jemt in their analysis of distortion of implant frameworks[82]. Their technique involves setting up a specific camera arrangement with mounted reflective mirrors that are used to simultaneously generate three images. In doing this, the researcher

is able assess the three-dimensional orientation of the 'top margin' of implants and gold cylinders in a prosthesis. It is a comparison methodology; therefore photos are taken before and after any intervention, say a framework attached to a master model before and after processing, which are then superimposed using software for an interactive three-dimensional translation[66]. The technique detailed by Lie and Jemt assesses the fit using these superimposed images where centre points are compared to the peripheries on each image. Of note, the technique is able to measure a gap of 30 μm[82], but has been shown by Mulchay and colleagues that standardisation of the images and camera positioning is difficult[83].

The final dimensional technique described by Abduo is the use of a coordinate measuring machine, a commonly used device in industry by engineers and machinists for measuring the physical geometrical characteristics of an object and dually for the purposes of quality control and quality assurance. Each machine consists of a probe that is attached to the third moving axis of the machine; it is this probe that is positioned to measure a components size in three-dimensions. Some machines are automated and some are manually operated, however each is connected in some capacity to a computer for specific analysis of the object being measured. Mulcahy reported that manufacturers of these machines have claimed accuracy at the level of 1 μm[83], with other previous studies having used coordinate measuring machines for analysis of framework fit and distortion[66]. Machines are typically expensive (AUD$10,000 to AUD $200,000 or more) and large, requiring considerably more space than either conventional light microscopes or a photogrammetric technique setup. As a result, this is an in vitro

technique only and it would be rare for a commercial dental laboratory to possess one of these machines.

In Vitro Methods to Assess Framework Fit[66]

Method	Advantages	Disadvantages	Accuracy
Modelling Methods			
Photoelastic stress analysis	Provides location of stress Qualitative method	Not able to model living tissues and prosthesis Limited parameters can be assessed Underestimate the stress Uses isotropic model	++
Strain gauge analysis	Simplifies complex situations Quantitative Can be used intraorally on the framework Useful if used with materials that mimic natural tissues	Location of the strain gauge is critical Gives reading only at the site More two-dimensional than three-dimensional No subsurface information Sensitive to temperature changes	++++
Finite element analysis	Precise Predictable Can handle multiple parameters Excellent in quantifying stresses Can assess the effect of inaccuracies Provides insight about implant-bone interface	Complex to use Basis of assumptions and boundary conditions of model are critical	+++++
Dimensional Methods			
Microscope	Easy to apply and interpret Low cost Can be used in dental laboratory	Requires standardisation Variable accuracy Not efficient in three dimensions	+++
Photogrammetric	Provides three-dimensional assessment Accurate	Requires specific software Standardisation of camera position is mandatory Technique sensitive	++++
Coordinate measuring machine	Repeatable Accurate in 3D	High Cost Special facilities are needed	+++++

Table 2: In vitro methods for assessing implant framework misfit, table reproduced from Abduo and colleagues

2.5 Periodontal versus Periimplant

There is an inherent difference between the physiology of periodontal tissue and the tissue that surrounds osseointegrated dental implants. Natural teeth have what may be perceived as a built-in safeguard to deal with tooth-supported restorations expressing misfit, research in periodontometry has revealed natural teeth can exhibit bucco-lingual movement between 56μm and 108μm and an intrusion of 28μm under applied load[38]. The ability to move under load, effectively allows teeth to exist with a built-in springboard not available to osseointegrated dental implants.

An ideally integrated dental implant is completely surrounded by bone, a non-resilient interface that allows minimal movement of the fixture due to the lack of immediate deformation of bone when placed under load. When force is applied to natural teeth, it is transferred to the periodontal ligament, which effectively acts to cushion incidental force vectors. The periodontal ligament is known to be a non-linear, visco-elastic material, with applied forces leading to both compressive and tensile forces applied. An overload of this system, will initiate an orthodontic response, allowing the tooth to migrate through the activation of osteoclast and osteoblast activity both ahead of, and behind the tooth in question[84].

Conversely, an implant will transfer incidental force vectors to the surrounding bone as described by several authors, including Clelland and colleagues[61]. This is a rigid connection that will transmit any stress and/or strain that results from the fixation of prostheses to the implant directly and thus transmitting this to the

bone-implant connection. Any force noted in this event, is exacerbated by the affect of dynamic intra-oral loading[38].

Szmukler-Moncler and colleagues however considered the dynamic nature of the bone-implant connection. While previously they considered a static connection with zero displacement in terms of micro-motion, the authors described a range whereby specific movement of the fixture was possible; the subsequent outcome being that of osseointegration which is able to prevail over that of fibrous encapsulation. The stated range identified in the study is between 50μm and 150μm[85], indicating that osseointegrated implants are able to tolerate the incidental force vectors within a given range. Similarly, Rieger and colleagues[86] reported that a range of stresses (1.4 to 5.0 MPa) appears to be needed for healthy maintenance of bone about implants. Stresses outside this range have been reported to cause bone resorption[79].Yet there still remains little human prospective study evidence in the literature regarding the affect occlusal forces are able to impart on the periimplant bone interface, which will be further discussed later.

2.6 Biological effects and the implant-abutment connection

The biological interface between periimplant bone and implants is a complex one. Since Brånemark first established the concept of osseointegration, implants have been restored with prostheses. Since that time, there has been very little in the form of rigorous scientific literature of a desirable evidence level to link biologic consequence and sequelae with imperfect implant-abutment connections. With that in mind, there are certainly instances within the scientific literature that bring

together the two concepts in an attempt to discuss or show causal relation. It is often that the predominant intervention that recalls both issues is opinion based or one of inferential and deductive reasoning, drawing upon similar theories that revolve around tooth-based restorations rather than implant-based.

Perhaps this is best demonstrated in the Sahin paper of 2001, where a brief description of the different interface between natural teeth and the jaws is contrasted with that that occurs between implants and the jaws. Being surrounded by a periodontal ligament, a tooth has a resilient interface that is considered dynamic under an applied load. It has potential to exhibit three-dimensional movement with recorded bucco lingual displacement between 56 μm and 108 μm and an intrusion of 28 μm[38], effectively acting as a cushion for the tooth when placed under dynamic load. Given time, the tooth is also able to migrate under said load if it is of a sufficient magnitude. The obvious contrast with dental implants is the lack of a periodontal ligament surrounding the external surface, acting as the interface to bone. The interface therefore is between bone and the dental implant alone and considered to be a rigid, non-resilient interface. The subsequent distribution of incidental forces is transferred along the implant and to surrounding bone. Sahin maintains that when a fixed prosthesis is connected to osseointegrated implants, off-axis or lateral forces subsequently applied may trigger adjacent cortical bone resorption, or may additionally appear as a prosthetic complication following the superimposition of functional stresses[38].

Abduo and Judge concede that negative outcomes may be expected following the apparent disguise of framework misfit by torque-induced implant displacement. There is however yet to be a finite element analysis (FEA) or animal-based study that supports such a supposition[57], citing examples where the opposite outcomes have eventuated – including greater bone deposition and long-term reduction of framework misfit, however examples of this nature are only derived from FEA studies or animal-based studies.

Within the literature there exists concern regarding the implant-abutment interface and the concept of bacterial leakage from within dental implants. The concept of oral microorganisms adhering to implant surfaces and forming dental plaque, has been reported in the literature, bacterial flora within the plaque become increasingly complex with plaque maturation[87]. The concern with respect to these microorganisms centres upon the idea of imprecise interface connections between implants and abutments; when not fitting correctly there is the potential for having a negative biological consequence not only on the prosthesis/implant system but also the conditions of the periodontal tissues due to a distinct alteration of the clinical and microbiological parameters adjacent to the imprecise interface due to increased microbiological growth[88]. Sources of potential microorganisms may arise due to contamination of the internal recesses of implants or associated cover screws and healing abutments used during first and second stage surgeries. Certainly there is also the presence of intra-oral microorganisms that may be transmitted from the oral environment into the internal surfaces of the implants after installation of the prosthesis- a result of the gap at the implant-abutment

interface. In an in vivo study, it was shown by Nakazato and colleagues[87] that after a four hour of exposure to an oral medium, it was possible for bacterial colony formation upon the surface of prosthesis componentry, irrespective of the materials used for the reconstruction (single-crystal alumina, partially stabilized polycrystal zirconia, hydroxyapatite and pure titanium). It is therefore possible that this may occur in relatively short time at the implant-abutment interface, in particular under conditions where the this interface is suffering from an imprecise fit. This is further reinforced by the Nakazato study, where in addition to finding the early colonisation of prosthetics, reported that surface roughness was a significant factor on the early adherence of microorganisms. Certainly such a finding has relevance upon the presence of imperfect implant-abutment interfaces, which by their very nature have an altered surface topography offering an inherent modicum of protection for microorganisms to promote their adherence. At the four-hour mark in the Nakazato study, the predominant species identified was *Streptococcus* species, with over 50% of the adhered cells. *Actinomyces*, *Neisserua*, *Veillonella* and *Lactobacillus* species were the remaining order of decreasing frequency. The bacterial distribution resembled the supragingival plaque commonly found on natural teeth[87].

2.7 Clinical perspectives on generic componentry

In a competitive market there are increasing pressures on clinicians to produce implant restorations at a reduced cost to patients. As a result it is expected that alternative solutions will be explored by clinicians when considering how to safely and economically offer the option of implant therapy for patients. This may

be in the form of cheaper fabrication methods or the utilisation of generic componentry within or throughout the fabrication process for a prosthesis.

In general terms, the restoration of implants is an area that has lent itself to wider uptake within the general dental community compared to surgical placement of implants, although this would seem to be changing in contemporary Australia with increasingly more clinicians offering surgical solutions. Practice setup costs to provide restoration of dental implants are comparatively lower than those required to offer surgical placement of implants, often only a torque limiting device/torque driver (estimated AUD$50-$200) and an impression coping (estimated AUD$40-$150) are all that are additionally required beyond a standard restorative dentist's armamentarium. In addition, a basic understanding of impression taking is often all that is required to achieve a subsequent basic restorative outcome, if that is all that is desired or being offered by the clinician. However, under guidance and with proper education, a higher level of restorative expertise can be achieved, although this may not necessarily always be sought.

To claim that one restoration is superior to another of a similar type from a clinical perspective, say a single implant-retained crown, offers a subjective view in many ways. From an aesthetic point of view however, there are publications that have dealt with objective parameters relating to dental prostheses in-situ. First described by Meijer[19] in relation to the implant restoration and the tissues surrounding it, the concept was further expanded with the describing of the Pink Esthetic Score (PES) by Fürhauser and colleagues[18] and the White Esthetic Score

(WES) by Belser and colleagues[89]. These objective measurements however don't consider the physical composition of the implant crown and the components that contribute to the observable features of the restoration. Rather, the usefulness of these objective scores assists in describing the completed result rather than what goes into achieving it.

It stands to reason that the use of proprietary restorative componentry, made and sold by the same manufacturer as the implant fixture, carries an expectation that componentry fit will be accurate and precise - accuracy being the trueness, or closeness of adaption and precision pertaining to the repeatability of this accuracy across a number of samples. By inference therefore, questions of fit arise when considering the use of non-proprietary componentry and thus how confident clinicians can be in the accuracy and precision of these components when employed in the restoration of dental implants.

As has been demonstrated in the literature by Pjetursson and colleagues[23,90], the vast majority of mechanical complications for long-term follow-up implant retained prostheses arise due to a compromised fixation of componentry and hence a de-stabilised connection between the abutment and an implant, with screw loosening being one of the more frequently encountered problems[91], particularly for external hex fixtures.

The essential requirement of screw joint stability therefore is dependent upon the integrity of the connection of the implant-abutment and the tolerance between

them[92]. We know that a screw will become loose when the bending force is larger than the clamping force produced by the preload of the screw and the settling effect between the screw and the internal surface of the implant. These issues are certainly capable of being modified in the presence of generic componentry that has not been specifically designed nor fabricated with proprietary knowledge of the tolerances required by the system. Binon considers the issue of tolerance between three different manufacturers of slip-joint external hexagon connection implants and their respective analogues.[93]The paper makes the comment that manufacturers had been encouraged to produce improved matrix (hexagonal abutment component) and patrix (implant hexagonal extension) hexagonal tolerances following the finding of a direct correlation between minimal rotational misfit and optimal screw joint stability. Across the implant manufacturers in the Binon study there was a range of 15 μm between their mean flat-to-flat dimensions. The relationship between the mean implant and analogue hexagonal size was perhaps the most interesting however, with each of the analogue hexagons being slightly smaller than the implant hexagon itself.

To attain a true and accurate hexagonal orientation and have this transferred to the working cast, we desire an impression post or transfer component to accurately fit with minimal vertical, horizontal and rotation misfit. We also desire that the hexagon itself and its spatial arrangement be essentially duplicated with the analogue, presenting analogous accuracy, fidelity and consistency as a mirror to the original hexagon.

Binon continues with his views on mismatching componentry between manufacturers, stating that when components are utilised within their own system, the rotational misfit (in the setting of an external hexagon connection) would be minimal, as would any potential proximal contact discrepancies by inference. However, as per his report, several external hexagon implant manufacturers utilise similar but not identical geometries; a crossover of componentry, where a larger implant analogue (say, 3iL analogue in the study) is used with a smaller implant hexagon (say, a Stryker implant fixture) then a significant rotational and proximal misfit may ensue. He continues with this thought process, stating that cumulative rotational tolerance errors (implant hexagon, impression post hexagonal recess, analogue hexagon and UCLA gold cylinder/abutment geometries) could theoretically add up to rotational errors of seven to ten degrees. A recommendation of using close tolerance components from the same manufacturer whenever optimal rotational indexing and hexagonal stability is necessary.[93] In a previous study, Binon reported that rotational misfits greater than five degrees result in more rapid screw loosening[94]. The three external hexagon systems analysed in the original study exhibited greatly improved tolerances from 1.6 to 5.3 degrees versus another previous Binon study that found rotational misfit values from 4.0 to 6.7 degrees[95]. This demonstrates the manufacturers desire to improve tolerances, accuracy, fidelity and consistency in their respective componentry.

In terms of a clamping force, the internal-connection fixtures may have a different interaction with their respective componentry, at least in terms of single implant

restorations. With certain abutment designs or orientations, there is potential for creation of a wedge-type effect between abutment and the internal aspect of the implant as they more closely approximate each other during screw tightening. This may lead to a greater influence of frictional resistance versus screw preload on the stability of the connection. The joint may appear stable for all intents and purposes, however it has been shown that the detorque value of an abutment screw in an internal-connection implant decreases after the axial displacement of the abutment[96].

Lee evaluated screw joint stability in a study comparing customised generic abutments of differing metals: titanium versus a precious alloy (palladium 30-40 wt %, indium 30-40 wt %, silver 20-30 wt %, gold 1-5 wt % and copper 2-10 wt %). The implant-abutment interface was an internal hexagon design of the GS III implant manufactured by Osstem (Seoul, South Korea). A procedure used to test joint stability has been reported in earlier studies, with the most universal method being to investigate micromotion after applying dynamic loading using a strain gauge or measuring the detorque value of the abutment screw with the help of a digital torque gauge[92,97], Lee and colleagues utilised the latter methodology. The study's aim was to compare two materials by means of a noninferiority comparison, essentially looking to see if the experimental alloy was able to perform to the clinical level expected of a titanium abutment. For the purposes of this literature review, it just so happened that the abutments themselves were generic abutments for the particular implant system.

Initial detorque values, prior to loading demonstrated no statistically significant difference (P = 0.13) between the titanium and precious alloy abutments (control: 24.3 ± 2.6 Ncm^{-1} versus precious alloy: 22.8 ± 2.1 Ncm^{-1}). The authors felt that the precious alloy group displayed a competitive initial detorque value compared with the titanium abutment, which they considered appropriate for clinical use. Following simulation of one year of human mastication (10^6 cycles ranging from 0 to 320 N with a sine wave of 14 Hz) there was a marked decrease in detorque values for both groups (control: 9.7 ± 1.8 Ncm^{-1} versus precious alloy: 12.7 ± 1.5 Ncm^{-1}) with the two groups being significantly different from the other (P < 0.01). Interestingly the detorque value difference between pre- and post-loaded values for the respective groups was a smaller change for the precious alloy group, again with a significant difference (P < 0.01) between the two groups (control: 14.7 ± 3.1 Ncm^{-1} versus precious alloy: 10.1 ± 2.6 Ncm^{-1}). Results were able to demonstrate that both the control (titanium) and the experimental precious alloy had significantly lower detorque values.

Within the same study the authors examined the precision of the abutment screw joint using a surface measuring system, similar to a coordinate measuring machine. The mean abutment-implant gap for the titanium group was 12.2 ± 2.0 µm and 13.3 ± 3.7 µm for the precious alloy group, with no significant difference between the two groups (P = 0.76). The average difference between the two generic abutment types was 1.1 µm, a distance considered to be almost

clinically identical[62]. Lee and colleagues consider one of the potential sequelae of having a microgap present, discussing the findings of Passos and colleagues, who looked at microbial colonisation of the internal aspect of implants[88]. Passos maintained that even with a microgap or Implant Abutment Interface (IAI) of less than 5 μm, it was possible for *Escherichia coli* to invade the space. These microorganisms have a diameter of 1.1 to 1.5 μm and length of 2 to 6 μm and can be found in a variety of implant systems. However, Passos felt that implants that possessed a hexagonal, tapered internal connection had a much better capacity to seal against colonisation[92].

2.8 Anatomy of the Implant Abutment Connection

Various implant manufacturers have developed a variety of implant-abutment connection designs. This connection, or interface, lends itself to classification based upon the respective geometries. It was proposed by Dittmer and colleagues that allocation of the various connections into two rough groups can occur[98]: either butt joints/slip fit joints or conical connection type joints. The former possess interface designs with a passive connection and a slight space between implant and abutment[93], whereas the latter possess conical interface designs with friction fit joints. Of note, both types are able to be sub classified into internal and external connection types. Internal connection types are characterised as having the connective process of abutments placed within the implant body, by comparison external connections types are characterised by the connective process of an abutment enclosing an extension of the implant body[98]. Authors have also classified implant-abutment connections designs with respect to the lock

against rotation by an index at the implant-abutment interface. An index in this situation is useful in transferring the model cast situation to the in vivo situation by avoiding displacement and rotation of the abutment in the fixture[98].

The external hexagon (external-hex) configuration on external-hex implants was initially designed to facilitate implant insertion. This primary function evolved however, becoming useful to restorative clinicians for indexing prostheses and for the purposes of anti-rotation[91,95]. They are named as such when the connective aspects of an abutment enclose an extension of the implant body[98]. This initial design as proposed by Brånemark, was incorporated into a variety of competing implant systems, having proven popular at the time. Despite this, the design contained inherent flaws, primarily due to the limited height of the external hexagon geometry, 0.7 mm, that was relatively ineffective at resisting off-axis loads[91,99]. Several authors investigated the ability of the external hexagon to stand-up to these types of loads, speculating that the connection lent itself to increased movement on a microscopic level between the mating components when subjected to these loads, ie- micro-movement. It is this movement however that in turn may result in the loosening of abutment screws and/or fatigue fracture of components [6,100,101]. Binon reported that horizontal fitting errors in external-hex connections resulted in implants and their internal screw parts deforming on tightening[93]. It has been shown that this deformation has an affect upon joint stiffness, fatigue resistance, preload retention, and contributes to screw loosening[93].

It was suggested in Gracis' paper[91], that internal connection implants were subsequently introduced to lower or eliminate mechanical complications, thus reducing the stress that is transferred to the periimplant crestal bone. Norton demonstrated that the internal conical joint was a significantly more stable joint when compared to an external hexagonal or butt joint, in resisting extreme bending moments in a 3-point bending test[102]. In the same study, Norton established for external-hex connections, there is a critical zone of failure at the neck of the abutment screw, which is considered the "weak link in the chain" for these connections. By comparison, conical joints have no resistance to rotation, one of the prime benefits of the external- hex joint.

There are a number of stark differences amongst the various internal connection systems however, thus making it questionable as to whether or not all internal connection configurations offer reduced mechanical complications. Möllersten and colleagues investigated a number of implant systems with various implant-abutment interfaces, reporting that so-called "deep joints" exhibited better load bearing capacity than connections with a relatively short overlap of implant and abutment[103]. It is important to note that despite a range of failure modalities across the seven implant systems investigated by Möllerston (bent or fractured screws or abutments), there was no characteristic failure mode typical for a specific design of implant-abutment connection[98].

Dittmer's study considered six different implant-abutment configurations; five of the six systems were internal connections with the final specimen being a Nobel

Biocare external-hex implant to act as a control. The study aim was to evaluate the static load bearing capacity of clinically established implant systems of varying connections; with failure modes assessed using light microscopy.

Astra Tech Osseo Speed (Internal conical interface/hexagon, double hexagon), Bego Semados (Internal butt joint with short internal conical matrix/hexagon), Camlog Screw-line (Internal butt joint/3 possible positions), Friadent Ankylos (Internal conical interface/no index) and Straumann Standard (Internal conical interface/octagon) were the specimens of choice from the internal connection group, with the Nobel Biocare Mk III (External butt joint/hexagon) implant acting as the control. In the study, the load bearing capacity of the joint was determined as the maximum force occurring before failure, with failure considered to occur when a 100N load drop had occurred. Load was applied 30° off axis according to the standard for fatigue testing of implants and abutments (ISO 14801).

Load bearing capacity results were significantly lower for Straumann, Friadent and Astra Tech specimens than for Camlog and Bego specimens. In addition, there was no statistically significant difference in load bearing capacity between the results of the external-hex implant (Nobel Biocare) and the internal connection specimens[98].

The failure mode for each of the six specimens was reported also. It was determined following the testing procedure, whereby the authors embedded each specimen in a clear methyl methacrylate, sectioning each at a mid point along a

longitudinal axis with a diamond saw. This then permitted review of the specimens under a reflected light microscope. The authors did not make any mention of how these specimens were further processed in order to prevent artefact deposition of metallic shavings following the sectioning procedure, however given that the evaluation of the failure mode is largely observational, this may not contribute to errors as it may have in a quantitative evaluation.

For the Straumann group, the internal conical connection of screw and abutment was distorted, with the abutment being dislocated upwards. The abutment screw remained nearly intact, whereas the implant neck itself was bent upwards.

The Friadent group experienced displacement of all abutment screws upwards against their threaded bushings, with considerable thinning of the screw shaft at the entry point to the fixture itself. In one specimen the Friadent abutment screw fractured. From a functional point of view, while the abutment stayed essentially intact, large deformations where noted in the implant fixture itself that were accompanied by gap formation between at the implant-abutment interface.

The Astra Tech specimen exhibited slight abutment deformation in addition to deformation of the abutment screw and implant to a similar magnitude. The Astra Tech specimens had the deepest connection of all the internal connections examined in this study, results showed that while there was a gap in the upper area of the conical connection between implant and abutment, for the deeper

portion of this interface no observable gap was demonstrated, still maintaining a tight contact between parts.

For the Nobel Biocare external-hex specimens, there was minimal deformation of the abutment, however for all of these examined, the implant body fractured in the region of the butt joint connection. Each abutment screw was found to be deflected and clearly showed dislocation of the abutment itself.

Camlog specimens demonstrated minimal deformation of abutment or abutment screw, however aside from one instance, all implant fixtures fractured between the third and fourth outer thread on the side of the load application.

Bego specimens demonstrated distorted abutment screws in all instances, with abutments considerably dislocated and obvious gaps between the abutment and implant necks.

One of the interesting results to come out of the Dittmer study is the macroscopic observable differences seen under reflected-light microscopy of each specimen type and the comparison of load bearing capacity values (*figure 1*). While each specimen had a pre-determined fail point (when there had been a 100N load drop), the point when this occurred was different for each manufacturer. The mean load bearing capacity for the Astra Tech specimens was relatively low at 768 N compared with Bego specimens having a mean of 1129 N. However Astra Tech specimens still maintained a seal in the lower portion of the implant-

abutment interface with less distortion and only minimal gap formation when compared with the Bego specimens that had stark abutment gaps. This raises the question as to whether one design over another is better suited to contend with off-axis loading: a design like the Astra-Tech Osseospeed that develops a load drop earlier and therefore has less overall distortion of componentry or a design such as the Bego Semados that is comparatively more resistant to off-axis loads, having a force drop at a higher level, but with more catastrophic effects on the associated abutment, abutment screw and fixture interfaces. The mean load bearing capacity for the remaining specimens was: Camlog (999 N), Friadent (624 N), Nobel Biocare (944 N) and Straumann (606 N).

Additionally, the authors reported on the forces needed to initiate plastic deformation for each of the specimens, with mean values as follows: Astra Tech (430 N), Bego (955 N), Camlog (891 N), Friadent (368 N), Nobel Biocare (635 N), Straumann (456 N).

As concluded by the Dittmer study, the failure mode of the varying designs differs with the various implant-abutment connections and it would seem that the design itself has a significant influence on the load-bearing capacity of implants. Long opposing lateral surfaces of implant and abutment, the so-called friction fit surface, seems to have advantages with respect to load-bearing capacity in comparison to connections that have a relatively short overlap of implant and abutment[98]. It is important to note that the load bearing capacities used in the study all exceed the average clinical force imparted upon implant complexes

intra-orally, and are considered to be much higher than average chewing forces. Thus, the components tested in the Dittmer study could be expected to withstand clinically relevant forces without succumbing to the types of failure modes in the study that were noted under light microscopy.

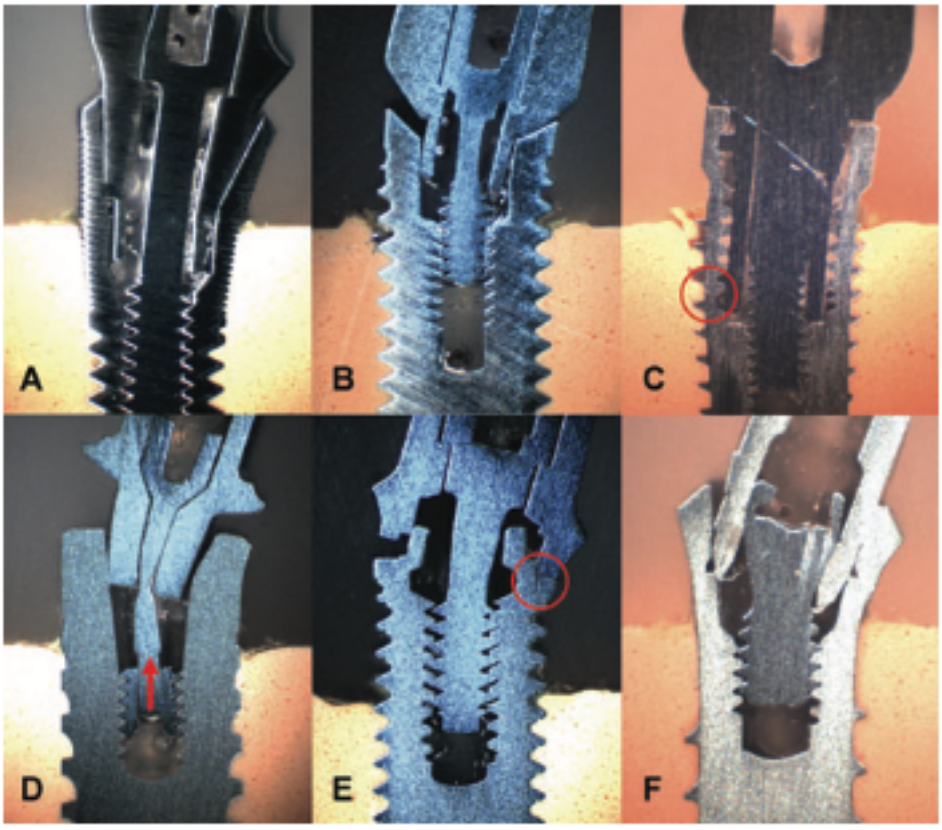


Figure 1: Polished cross-sections of embedded failed specimens of the different implant-abutment connection types, viewed under light microscopy: (A) Astra Tech; (B) Bego; (C) Camlog, red circle indicates implant body fracture; (D) Friadent, red arrow indicates displacement and direction of screw bolt against threaded bushing; (E) Nobel Biocare, red circle indicates fractured implant body; (F) Straumann. Image and annotations courtesy of Dittmer and colleagues[98]

2.9 Anatomy of a Dental Implant Abutment

A dental implant abutment is an integral component in the prosthetic restoration of implants. It functions dually as an *interface* and a *supporting structure*. As an *interface* between implant fixtures and their prosthetic rehabilitations, it intimately approximates itself against the implant fixture; in addition it acts as the *support* for the various prostheses used in implant reconstructions, either directly or indirectly.

There are generally two abutment types: one-piece or two-piece, with all possible variations being a derivative of these types. A two-piece abutment comprises two distinct units: primarily an abutment with a separate retention screw, differing from one-piece abutments where the screw thread is built into the abutment. In terms of retention, the one-piece abutment is entirely dependent upon either the frictional force of opposing surfaces or preload imparted on the incorporated screw thread. A two-piece abutment on the other hand, generally incorporates a design feature that provides additional stability. For an internal hexagon, it is common to encounter this feature as an anti-rotational process incorporated into the male aspect of the abutment (although this is not always the case); this internal hexagon for two-piece abutments makes contact with the corresponding internal hexagon within the implant, an abutment thread/bushings are positioned lower within the implant; an example of this design is the Neoss ProActive fixture which incorporates an anti-retentive deformation lug at the terminal aspect of each hexagonal face. An alternative to this design is the internal cone, with the additional incorporation of an angled internal wall within the implant. This feature

is used primarily to provide a more intimate seal of the implant-abutment connection; its secondary function is to guide the abutment towards the true mid-point of the fixture and facilitate final seating of the abutment. Commonly, there will be an anti-rotational feature at the apex of the internal cone fixture, such as the NobelBiocare® Conical Connection implant, which additionally acts to locate or guide the abutment into place and reduce the rotational movement of the abutment within the implant.

Norton compares the relative strengths of one-piece and two-piece conical abutment joints[104] as an extension of the work he completed in an earlier study comparing solid conical abutments with external hexagon butt-joints retained by retention screws[102]. One of the concerns he raised over the two-piece conical abutment joint was in regards to the retention screw, as his earlier comparison with external hexagon butt-joints found the retention screw to be the "weak link" of the construction. The results of both one-piece and two-piece conical abutment joints were overall very favourable in response to the 3-point bending test (considered by Norton to be the most appropriate method for testing the strength of a joint, without influence of dynamic movement of fatigue).

The mean bending moments necessary to plastically deform the one-piece and two-piece abutments are impressive, with values of 4176 N mm and 4049 N mm respectively. This compares quite significantly to results of the 1997 study when considering the butt-joint external hexagon connection returned a 3-point bending result of 645 N mm[102].

The critical zone of failure for the one-piece and two-piece abutments differed: the one-piece abutment mechanically failed with bending of the solid abutment at the "edge of the beam" or adjacent to the incidental force. Significantly, this is away from the abutment-implant interface and may therefore pose a benefit of this joint design providing greater resistance to bending. No one-piece abutments loosened or fractured during the evaluation. The hollow two-piece abutments had a critical zone of failure at the head of the abutment screw and additionally at the deepest level of the internal hexagon itself. Through observation of the linear elastic curves (displacement vs bending moment) smaller deformations (~50%) occurred per unit of load within the two-piece abutment design compared to the solid one-piece abutment, further indicating the rigidity of this joint in resisting displacement, even at high loads.

An interesting phenomenon was reported in the 2016 Lee study with respect to the implant-abutment connection and abutment removal after the detorque analysis described previously in this literature review. As previously mentioned, the abutment used by Lee and colleagues was a two-piece, customised, generic abutment. In the study, the two-piece conical abutment was torqued into place as per manufacturer guidelines to 30 Ncm^{-1}; it was then retightened after 10 minutes to reduce any potential settling effect. Specimens underwent cyclic loading that equated to 1 year of human mastication (10^6 cycles). After this loading procedure, the abutment sank down onto the interior aspect of the implant, with Lee describing the interface as being cold-welded together. It has been described by

other authors that a connection is considered cold-welded when detorque values were increased after cyclic loading[105]. The specimens in the Lee study however had detorque values lower than the pre-loading torque values at the beginning of the experiment, suggesting that the Sutter definition is not carried in this instance. Lee considers the ductile nature of the generic abutment materials and their geometry however, noting that the precious alloy (Pd-Ag alloy) and the UCLA gold abutments experienced plastic deformation from the loading protocol. Lee proposes that perhaps the direct contact relations between the abutment and implant need to considered as well rather than simply looking at detorque values when considering the phenomenon of cold-welding. The wedge shape of deep internal conical connection abutments may have a noticeable influence when the ductile natures of various abutment alloys are considered, particularly with wide variation amongst implant systems and the degree of internal taper for deep cone connections.

2.10 Computed microtomography (micro-CT)

The term Tomography is defined as imaging by sections and is a derivative of the Greek words, *tomos*, meaning "slice or section" and *graphō*, meaning "to write." While there are many credited with conceptual development of tomographic systems, the first theoretical patent was lodged by Frenchman, Andre-Edmund-Marie Bocage in 1922. This was then followed by Italian, Alessandro Vallebona's first functioning device in 1930, which was introduced at the Italian Congress of Radiology that year and demonstrated the ability to create a tomographic image from his own theories independent of what others had done before him.

The concept of x-ray computed tomography (CT) imaging was first developed in the 1970s where investigators considered a number of different techniques designed to reconstruct conventional tomograms from digital date acquired by different methods: laser film digitisers, image intensified digital fluoroscopy, direct digital data acquisition from digital radiographic slit scanning of electronic x-ray detectors, and photostimulable phosphor imaging plates. The thinking behind this evolution is based in the idea that since these kinds of images are computer constructed anyway, any subsequent digital reconstruction of the data allows an improvement of the image versus conventional tomographs. This included blur reduction, edge enhancement techniques, and contrast control with gray scale windowing. With increasing availability of computers and the advent of the transverse axial scanning method, the first commercially viable CT scanner was introduced by Godfrey Hounsfield[106] and based upon the mathematical theorem known as the Radon Transform (a creation of Austrian mathematician, Johann Radon in 1917).

Today, most CT machines utilise the spinning tube setup, more commonly known as spiral CT whereby the entire x-ray tube is spun around the central axis of the area being scanned. Typically, these modern clinical scanners are able to produce images composed of $1mm^3$ voxels (elements of volume in three-dimensional space); however a comparison with the power of computed microtomography (Micro-CT) is stark, with resolutions vastly more detailed. Since the first Micro-CT system was introduced in 1982 by Elliott[107], these systems have been able to

resolve voxels in the range of 5-50µm, which equates to approximately 1,000,000 times smaller volumes than conventional CT scans[108].

As per the definition, the basic principle behind tomography is the obtaining of virtual cross-section slices of a desired object, permitting a view of the internal aspects of the object without having to physically alter it or destroy it. The general basis of Micro-CT is an x-ray transmission imaging technique (figure 2). With the desired object sitting between an x-ray tube and a detector, x-rays are emitted from the x-ray generator, travelling through the sample and are recorded by the detector on the other side. The sample is then rotated by degrees, while simultaneously being energised by transmitted x-rays. All the while, projection images are being recorded by the detection device as the sample stage is rotated through 360 degrees. Each image slice represents a spatial distribution map of linear attenuation coefficients determined by the energy of the x-ray source and the atomic composition of the sample[109]. Computer software is then able to collate the image slices of the sample's cross-sections and reconstructed (if desired) into three-dimensional models or renderings of the sample being scanned.

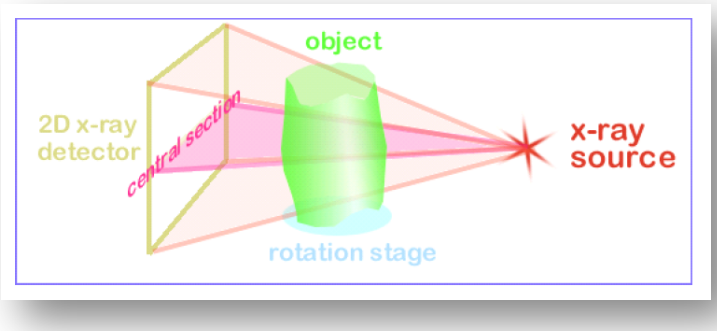


Figure 2: *Schematic representation of Micro-CT process. Image courtesy of www.microphotonics.com*

With excited x-ray photons produced via the firing of electrons at a tungsten/copper target anode, these are transmitted to and through the sample on the rotation stage. The finer detail achievable with Micro-CT is possible due to both the intensity of, and how fine, the electron beam is. The smaller, yet more intense the beam of x-rays is, the higher the image resolution becomes. Micro-CT relies on the ability of samples to undergo both *partial absorption* and *differential absorption* of x-ray photons; essentially requiring that some photons are absorbed into the material, with others being transmitted to the detector in the case of partial absorption. Whereas differential absorptions relies upon the varying absorptive characteristics of materials to provide the different levels of contrast – without this phenomena the only image that could be derived would possess a uniform grey appearance.

There are several mathematical equations pertaining to the physics of computerised tomography, however to achieve an image at the x-ray detector the absorption and transmission of x-rays, as described above, are key factors. Hence, (in figure 3) the mathematical representation of this is summarised in the equation for x-ray attenuation:

$$I_1 = I_0 \cdot e^{(-\mu t)}$$

Figure 3: *X-Ray attenuation equation; I_0 = x-ray intensity before reaching object; I_1 = x-ray intensity after passing through object; e = the exponential coefficient; μ = the x-ray attenuation coefficient; t = the thickness of the absorbing material*

With the unabsorbed x-rays being recorded by the detector, a single radiographic image is produced, quite similar to a two-dimensional x-ray image. A series of these images are produced as the sample stage is rotated around 360 degrees. With thicker and denser materials, like bone, absorbing more x-rays than less dense materials, like soft tissue, the resulting image is a summation of the x-ray attenuation equation.

It is important to note that a sample's atomic number is relevant in the context what is examinable. If a sample is too high in the periodic table, ie- has a high atomic number, then the x-ray photon energy is insufficient to pass through the sample and produce an image at the detector. An ideal example of this is lead (Pb) with an atomic number of 82; so ideal is it at absorbing x-rays, that it is used as a shielding system for x-rays when only a few millimetres thick. In terms of dental materials, the same can be said for gold (Au), with an atomic number of 79, and even zirconia (Zr), with an atomic number of 40: both of these materials are considered dense in terms of x-ray absorption and produce stark white images on two-dimensional x-rays. Any consideration of using these materials for analysis in a Micro-CT array would be difficult, with imaging only able to capture the gross external shape of the sample, and being quite unable to see inside the respective structures. Certainly this would then defeat the purpose of analysis using Micro-CT, with the aim being a non-destructive analysis of the internal aspects of the sample. The converse can also be true when the atomic number is low, with reports of difficulty imaging less dense objects, such as pure Beryllium (Be), with an atomic number of 4 giving rise to low attenuation rates. As most biological

matter, whether bone or soft tissue, is comprised essentially of the elements: carbon (C, Z = 6), nitrogen (N, Z = 7), oxygen (O, Z = 8), hydrogen (H, Z = 1), calcium (Ca, Z = 20) and phosphorous (P, Z = 15) we know the range of atomic numbers that are suitable for appropriate x-ray attenuation as we have been taking human x-ray images in one form or another for more than a century.

The analysis of Titanium (Ti) however, with an atomic number of 22, raises the question as to whether micro-CT is an appropriate analytical tool. There are examples in the literature where titanium has been successfully analysed using Micro-CT, often in conjunction with an assessment of periimplant bone[110]. If we were to consider a two-dimensional dental x-ray image as an example once again, Titanium in the form of implants or prostheses certainly appears visible with a relative opacity that is easily differentiated on the film as being metallic. Often, if the angulation is correct and perpendicular to the object, it is possible to 'see inside' the implant and observe the abutment screw and thread of the connected prosthesis. Given that Micro-CT is essentially using the same basic x-ray photon excitation process, the same bombardment of the object with x-rays is occurring. It is not inconceivable therefore, for the analysis of titanium dental implants and their respective prostheses to be non-destructively analysed using Micro-CT.

One of the side effects of metallic evaluation with x-rays, and specifically CT scans, is the variable scatter and absorption that arises due to the increased density of the metal versus biological matter. The production of inherent halation artefacts adjacent to the titanium are known as 'partial volume effects' and are able to

influence the clarity at metal boundaries[108]. Manipulation of beam strength and attenuation factors within the reconstruction software are able to improve the quality of attained images and virtual models, however there are limitations. If specimens are too thick, then penetration of the x-ray photons will not occur, creating inherently white images of comparative 'under-exposure'. Fortunately implant specimens are essentially screws with a hollow cavity within them. This permits the variable *partial* and *differential* absorption of the x-rays as they pass through the comparatively thin outer wall of the dental implant overlaying the internal hollow aspect of the implant specimen versus the thicker, comparatively solid apex of the implant. The contrasting density provides an image of clinical interest, as opposed to a solid titanium rod, that would provide no internal structures and therefore limited clinical value.

Once the images have been taken in the Micro-CT array through the full 360 degrees of rotation, they are reconstructed through computerised stacking. The most common three-dimensional reconstruction algorithm, incidentally the first, was devised by Feldkamp, Davis and Kress in 1984 and is known as the FDK reconstruction algorithm. With the x-ray source trajectory being circular about 360 degrees, the resultant detector images produce filtered two-dimensional projections of the object being analysed. Through application of the FDK algorithm, these two-dimensional backprojection images are reconstructed into *virtual* three-dimensional models, permitting non-destructive analysis and manipulation – it is even possible to convert these virtual models into physical ones using 3D printers.

In reality however, the diagnostic value of images produced using Micro-CT are dependent upon the entire gamut of experimental artefacts such as image noise, beam hardening and ring artefact[111]. Shahmoradi and colleagues discussed the importance of noise removal in the analysis of Micro-CT images, stating that in the presence of impaired contrast and poor image quality, it can be difficult for image processing, and also for reconstruction algorithms to be effective. As a consequence, some of the key testing outcomes for Micro-CT: sample edge detection, segmentation of features and three-dimensional volume rendering, can be challenging in the presence of artefactual image noise. Shahmoradi discusses the common de-noising (denoising) algorithms for medical imaging, maintaining that only basic methods such as the gaussian and median filtering methods have been seriously used for Micro-CT and other maxillofacial imaging.

As per the Shahmoradi paper, gaussian filters are classed as linear filters. Their filter weight is chosen based upon the shape of a gaussian function or a normal distribution. With this type of filter, two initial arbitrary parameters are selected to form a two-dimensional matrix using this Gaussian distribution, these parameters are commonly the radius and standard deviation. Once the filter is applied, the transformation is applied to each pixel of the image. Median filters on the other hand are classed as non-linear image-smoothing filters that employ the median of the neighbouring pixels in the original image. All pixels of the pre-determined neighbourhood are sorted in order of 'grayness', with the median value calculated and set as the pixel value. Once the filter is applied, any surrounding pixels that

are different from the neighbouring ones are eliminated with the median value of pixels from within the pre-determined area being assigned instead. A separate denoising filter is compared in the paper, the block-matching and 3D (BM3D) technique, demonstrating the first time it has been proposed and used to for evaluation of dental Micro-CT images. It is a more advanced algorithm, performing the denoising process in three steps[111]:

1. Analysis – similar patches from the image are recognised and collected in groups with each group forming a 3D stack using an invertible 3D transform, allowing relocation of each patch of each stack to its original position in the image.
2. Processing – the 3D stacks are filtered by a hard-thresholding denoising method based on the wavelet transform
3. Synthesis – the filtered stacks/filtered patches provide an initial estimation of the denoised image for each patch. These filtered patches are then relocated to help form the newly filtered image, with the final image being calculated as a weighted average of the all the previously filtered patches.

As with all image assessment in Micro-CT, the diagnostic capacity and academic value of the image is only as good as the image filtering. With computers reconstructing all images through a volume rendering process, it is often inevitable that applying a filter is needed for denoising of the images to some degree. It is desirable for these filters however, to preserve as much as possible,

the relevant aspects of the samples being evaluated/scanned, including texture, contour and the finer details associated with two opposing surfaces. It was shown in the Shahmoradi study that each denoising approach has its assumptions, advantages and limitations and ultimately the selection of the respective algorithm is dependent upon the type of image, degree of noise modelling and the purpose of the analysis. They found that while BM3D algorithms were the most reliable for denoising images with very fine detail, such as shallow enamel lesions and other fine biological structures, they did not perform well in removing ring artefacts. By contrast, the Total Variation method, another technique described in the study, performed best when denoising images without very small details or fine textures where the goal is more structural and anatomical differentiation of features within and around a sample.

Micro-CT as a research tool in dentistry has been discussed in detail by Swain and Xue[108]. They report its recent advances as being an excellent empirical tool across several areas of interest in dentistry research, including: the relative quantification of tooth enamel thickness; analysis of root canal morphology and the evaluation of root canal preparations; non-destructive analysis of trabecular bone used in the analysis of craniofacial skeletal development (investigation of bone growth and repair); biomechanics in the field of Finite Element Modelling/Analysis (FEM/FEA), whereby more exact finite models of small objects like teeth, dental implants and restorations can be scanned and digitally reconstructed; tissue engineering with respect to characterising biological structures, scaffold architecture, *in vitro* scaffold degradation, and bone growth into polymeric and

calcium phosphate scaffolds; mineral concentrations of teeth – via a non-destructive slicing of teeth, irregularities that arise due to physical cutting of teeth are avoidable and differentiation between the mineral content of dentine and enamel can be defined; and the final application detailed by Swain and Xue involves the various interactions between periimplant bone and dental implants. They go on to explain the differences between histomorphometric analyses of the implant-bone interface and Micro-CT. It is common for the samples to incorporate artefacts as a direct result of sample preparation, additionally there are very few sections that can be made per implant specimen due to the challenges of the preparation procedure[112]. This obviously contrasts with Micro-CT, whereby an infinite number of sections in any orientation or plane can be non-destructively analysed.

Chapter 3 Materials and Method

Prominent implant manufacturers were contacted in writing, outlining the details of the proposed study. A request for donation of implant componentry (implant fixtures and proprietary titanium abutments) was included in the proposal to assist in reducing the financial burdens of the study. Within the correspondence it was detailed that both a proprietary abutment and a generic abutment would be attached to each manufacturer's implant fixture and analysed qualitatively using the non-destructive technique of computed microtomography.

Neoss Implants replied positively to the mail-out and subsequently donated the required implant and proprietary abutment stock for investigation purposes.

A manufacturer of generic implant abutments was also contacted and informed of the study aims and methodology. This manufacturer was asked to produce a titanium abutment using their internal production methods. In other words, an abutment produced in the same way it would have been if its destination had been for clinical use, rather than research purposes. As a result, the manufacturer requested a dental analogue be provided such that it could be used to reverse engineer an interface that could be attached to the proprietary implant fixture with a proprietary abutment screw.

Materials used during this study include the componentry of dental implants, the control and experimental abutment specimens, as well as the abutment retention screws. The specimens were scanned with the SkyScan-1076 in vivo Micro-CT

system (Bruker microCT, Kontich, Belgium) (figure 4) at Adelaide Microscopy (Adelaide, South Australia). Raw data was reconstructed using the software packages: NRecon and DataViewer (Bruker microCT, Kontich, Belgium) and subsequently analysed using Avizo 9.0 (FEI, Oregon, USA).

Figure 4: *SkyScan 1076 in vivo Micro-CT system (Bruker microCT, Kontich, Belgium)*

3.1 Components

3.1.1 Implant specimens

Dental implants used in the study were donated by Neoss Dental Implants (North Yorkshire, UK). This was made possible following a written request to participate in the study, with the implant fixture of choice being the Neoss ProActive implant. The size of the implant was 4.0 x 7.0mm and chosen as such to fit the specimen chamber during scanning with the microtomography unit. The Neoss ProActive implant is made from commercially pure grade IV titanium with a

surface produced through subtractive interventions, including: “multistage blasting, etching, cleaning and chemical treatment”[113]. Additionally, the implant has a bimodal surface that has been treated by “electrowetting”. This surface treatment is claimed to improve the wettability of the implant surface and thus promote accelerated healing and increased strength of osseointegration[113].

The implant has an internal hexagon-based connection, and thus six potential orientations. The implant-abutment connection is a press-fit connection, with the implant also having a short, non-engaging internal chamfer.

3.1.2 Abutment specimens

The Neoss system utilizes one abutment size for all implant diameters. A titanium proprietary abutment, sold as the *Ti NeoLink™ Mono* abutment (Neoss product no: 31133), was chosen as the control in this study. The Neoss implant connection utilises a unique design not seen in other systems and can still be considered relatively novel. The connection is a press-fit connection that offers an increasing platform switch or abutment-fixture mismatch as the implant diameter increases from 3.5mm to 5.5mm. A schematic representation drawing demonstrates the geometry of the Neolink abutment, including the dimensions of the various characteristics (in figure 5).

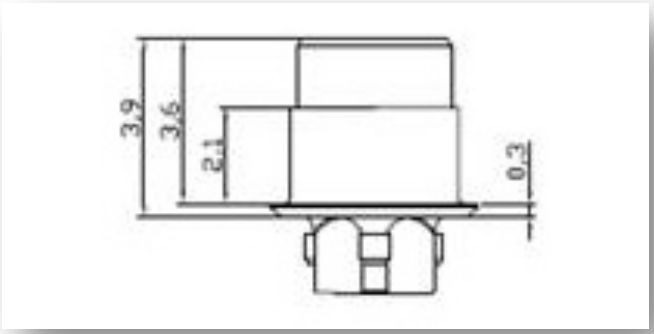
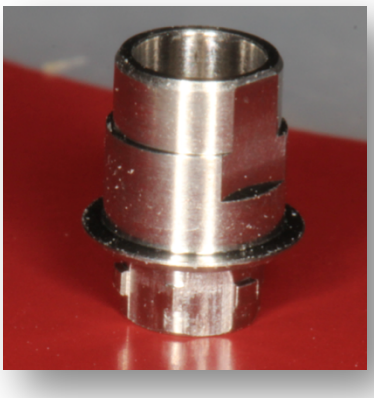


Figure 5: Titanium NeoLink™ abutment (measurements in millimetres)[113]

The NeoLink abutment (and all of the engaging abutments in the Neoss range) undergoes an intentional deformation of the anti-rotational lugs. These lugs undergo a characteristic change that is specific to the connection of one abutment to one implant and also specific from one of the six potential hexagonal orientations within the implant itself. By inference, the deformation of a lug within the implant will be characteristic for the particular rotational position that is selected for the abutment when it is first connected to the implant. If the abutment is then removed, rotated about the central axis and reinserted with an alternate rotational position (from say buccal to lingual), then the deformation lugs may be altered further or beyond the specifications of the manufacturer. Hence the fit will not be as intimate as that attained from the rotational angulation that was first selected when the abutment was connected to the implant. The deformation lugs can be seen in Figures 6 (a) and (b) from an inferior and superior perspective as extending laterally from the abutment connection cylinder. The intended proprietary contact points of the deformation lugs are shown in mesh schematic of Figure 7, whereby the extension of the lugs has a point contact

laterally on the internal hexagon. This point contact extends vertically for the entire length of the anti-rotation deformation lug.



(a) (b)

Figure 6 (a) and (b): *Photograph of Superior (a) and Inferior (b) view of the Ti NeoLink Mono abutment (Neoss Implants, North Herefordshire, UK). Noting the alternate areas at the abutment connection where the anti-rotational deformation lugs are present and when they are not.*

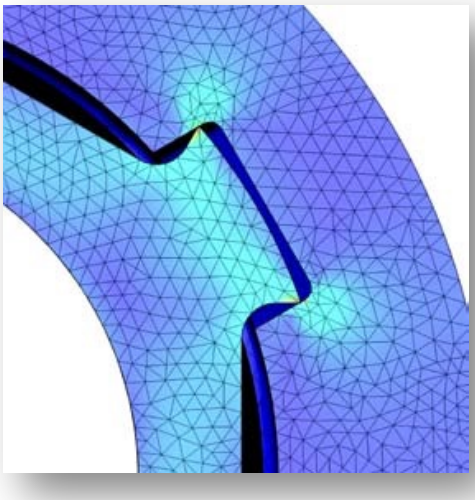


Figure 7: *Cross section of the anti-rotational deformation lugs making contact with the internal hexagon within the Neoss ProActive dental implant*[114]

A dental laboratory that also manufactures generic implant components, donated the generic abutments used in the study. These abutments were fabricated without direction from the author, using the laboratory's own in-house protocols. At the laboratory's request, a proprietary implant replica (Neoss product no: 31146) was provided to use in a reverse engineering capacity.

A Sheffield Discovery coordinates measuring machine (Hexagon AB, Stockholm, Sweden) was used to initially analyse the implant replica. This methodology was assessed as being the most accurate dimensional methodology to use by Abduo[66], citing the main advantages being that it is accurate in three dimensions and it is repeatable. Disadvantages cited by Abduo include the high cost of the machine and the need for specialised facilities. Fortunately, use of the Sheffield coordinates measuring machine was undertaken by Stoneglass Industries and thus full benefit of the most accurate measuring methodology was possible. Additional subsequent quantitative measurements were obtained with another machine, the Vertex 420 (Micro Vu, Windsor, USA). The quantitative measurements of the laboratory replica that were derived by both the Sheffield Discovery (Figure 8) and the Vertex 420 (Figure 9) were conducted by Stoneglass Industries staff and not divulged to the author. This was to ensure no bias was established in advance of connecting the generic abutments to the Neoss implants.

Figure 8: *Sheffield Discovery coordinates measuring machine (Hexagon AB, Stockholm, Sweden) at Stoneglass Industries*

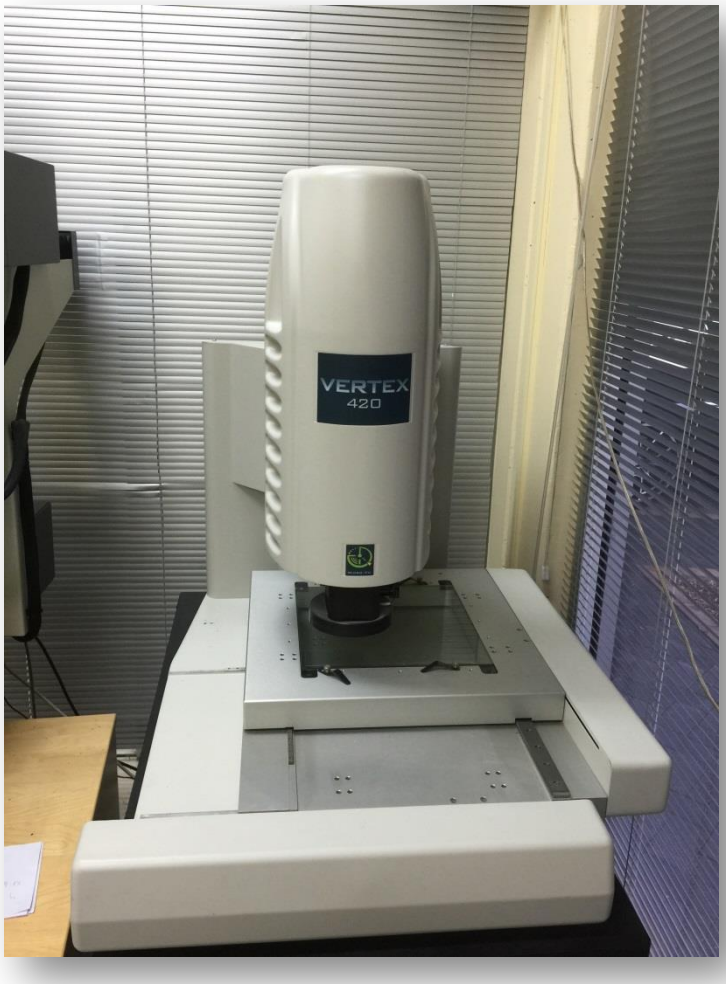


Figure 9: *The automated Vertex 420 (Micro Vu, Windsor, USA), used for quantitative measurement of the Neoss implant replica, at Stoneglass Industries*

This quantitative data is then loaded into a computer aided design (CAD) software package, SolidWorks (Dassault Systèmes, Vélizy, France), allowing the design of a three-dimensional CAD model to be produced of the implant replica. From this CAD file, the staff of Stoneglass Industries were able to design an abutment with a geometric shape they felt would best allow connection to the Neoss implant (figure 10). However, the design they chose was not a copy of the proprietary NeoLink abutment with its unique anti-rotational deformation lugs; rather it was a

simple hexagonal shape that was designed to complement the existing internal hexagon of the Neoss Implant. This is a prime example of alternative design geometries being created by generic manufacturers in an attempt to facilitate a workable connection.

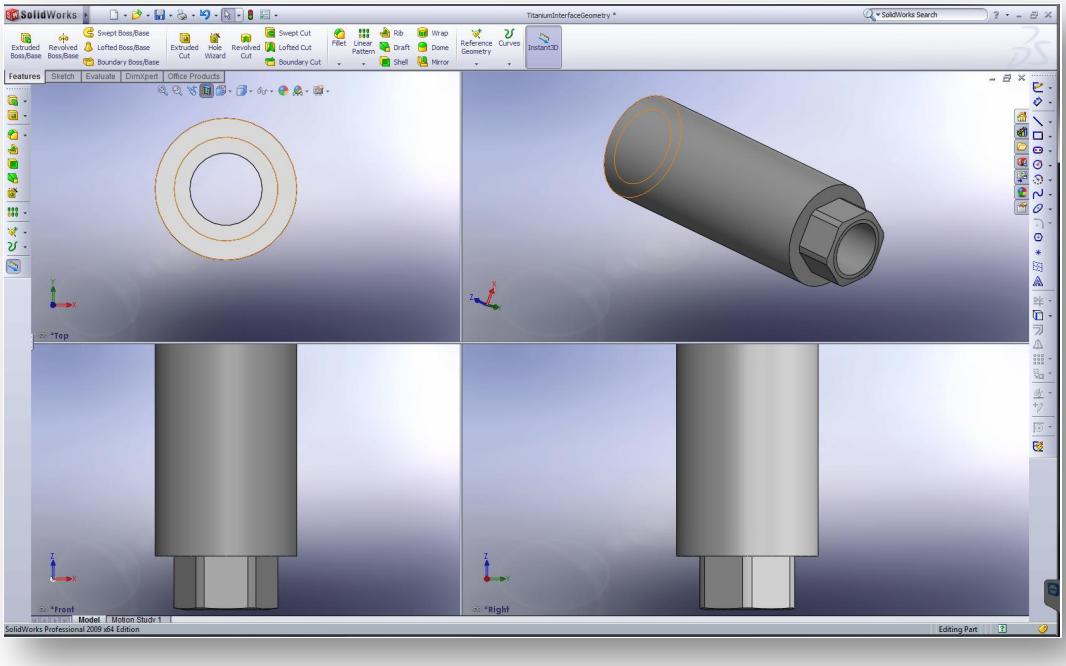


Figure 10: *CAD software, SolidWorks (Dassault Systèmes, Vélizy, France), used to produce a digital model of the replica, to then reverse engineer a connection for the third-party abutments. Image courtesy of Stoneglass Industries.*

A macro (a single instruction that expands automatically into a set of instructions to perform a particular task) had been developed (figure 11) in-house that was used for instructing the universal milling machine, DMU 50 eVo linear (DMG Mori, Bielefeld, Germany) (Figure 12), to conduct tool-cutting paths automatically. It is these tool-cutting paths that are used to machine an abutment

to connect with the implant replica that was provided to the generics manufacturer at the outset.

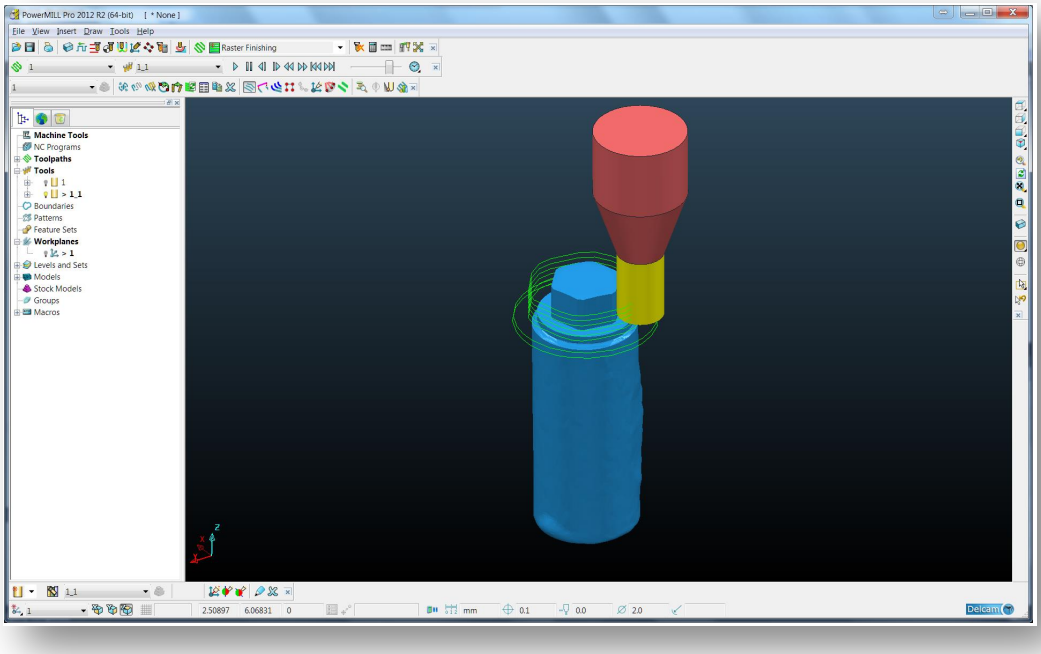


Figure 11: *CAD software, for instruction of the tool-cutting paths for the milling unit- the DMU 50. Image courtesy of Stoneglass Industries.*

The DMU 50 uses a titanium rod of 20mm diameter, with an initial trial run conducted to produce a test abutment. The Stoneglass Industries staff then perform a confirmation of this test-abutment by placing it into/onto the replica; fit is checked by hand using a light microscope. A soft touch is used to ensure fit is achieved passively and without interference; this subjective assessment was conducted by the Stoneglass Industries staff as part of their own internal quality control/quality assurance protocols (QA/QC).

Figure 12: *A universal milling machine, the DMU 50 eVo linear (DMG Mori, Bielefeld, Germany), which is used to mill the third-party abutments from a solid titanium rod of 20mm diameter at Stoneglass Industries.*

The dimensions of the internal hexed walls of this abutment are then fine-tuned as required by adding or subtracting 5µm in the original CAD file (Figure 10). Once this has been confirmed the seven abutments were machined by Stoneglass Industries for the study in a single run and used as the comparator to the seven proprietary abutments provided by Neoss. A photograph of the generic abutment

as it was received from Stoneglass Industries can be seen in figure 13. As there was no intention of using these abutments for clinical restorative purposes, the extensions tubes had been left intact, as had the sprues on the lateral aspect of the tube. With the desirable area of interest being the connection only, this hexagonal extension had been machined to the level demanded by Stoneglass Industries own QA/QC protocols.

Figure 13: *Photograph of a generic abutment used in the study. Note that the coronal aspect has not been fashioned to receive a crown restoration. For the purposes of the study, the only region of interest was the connection of this abutment with the proprietary implant specimens.*

3.1.3 Retention screws

Both proprietary and generic abutments were connected to proprietary implant specimens. This was achieved with 14 individual proprietary Neoss Crystal® screws (figure 14).

The design of these screws are considered proprietary information, however material in the public domain notes that they are composed of a grade 5 titanium alloy onto which a hard coating is applied. A layer of gold is then deposited onto this hard crystalline surface. Proprietary testing showed that this composition provided a 30% stronger abutment screw compared to the company's previous gold alloy screws in static strength testing. In addition, they report that the Crystaloc® screw demonstrated approximately 50% higher preload vs. conventional titanium abutment screws of the same geometry.[115]

(a)

(b)

Figure 14 (a) and (b): *Neoss Crystaloc® screws were used to connect all abutments to implant specimens in the study. These were considered single-use as per the proprietary guidelines*

3.2 Specimen preparation

3.2.1 Mounting device

A custom mounting device was constructed from a domestic white polyurethane cutting board. This device (figure 15a) was used to assist in a controlled, perpendicular, lowering of the implant specimens into a clear epoxy resin. The apical third of the implant was held suspended in the epoxy resin, which was contained in one half of a gelatin capsule (figure 15b). The aim of this was to permit a rigid fixation of the implant in a substance that would not cause any distortion to the implant fixture itself. The apical third only, was chosen as it was felt that this would be sufficient to rigidly hold the implant body in place when a subsequent torque was exerted on the implant. In addition, it was also felt that coating the entire surface of the implant with epoxy resin might unduly cause artefact during the micro-CT scanning.

The polyurethane board was measured and cut into equally sized pieces using a circular saw. Two longer slabs were used primarily as holding devices, able to hold eight specimens at a time – with one slab used to retain the laboratory abutment screws and the other to retain the gelatin capsules. Shorter lengths were used as equal spacers between these longer slabs

A vertical drill press cut straight holes in the upper slab such that laboratory abutment screw threads could be suspended from the underside of the polyurethane slab, with the screw heads themselves retained within the slab

through a friction grip. In addition, the drill press was used to cut retention holes in the lower slab to retain the gelatin capsules with a similar friction fit.

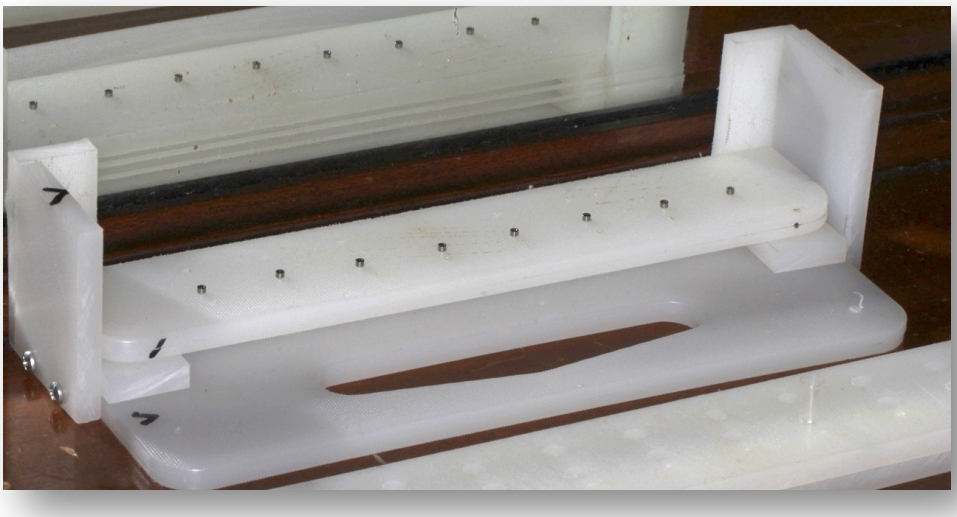


Figure 15 (a): *Custom polyurethane specimen mounting device. Holes were cut to 'friction' diameter, whereby abutment screws were used to passively suspend and lower implants into gelatin capsules containing epoxy resin. Abutment screws pictured.*

A spirit level was used to ensure that both the gelatin capsules and the abutment screw thread were parallel to the horizon. Implant specimens were hand wound to a stable position onto the abutment screws. Typically two turns of 360° was all that was required to adequately suspend the implant fixture in a stable position, ready for lowering into the capsule.

Figure 15 (b): A half gelatin capsule resting in the polyurethane block, awaiting epoxy resin and implant lowering.

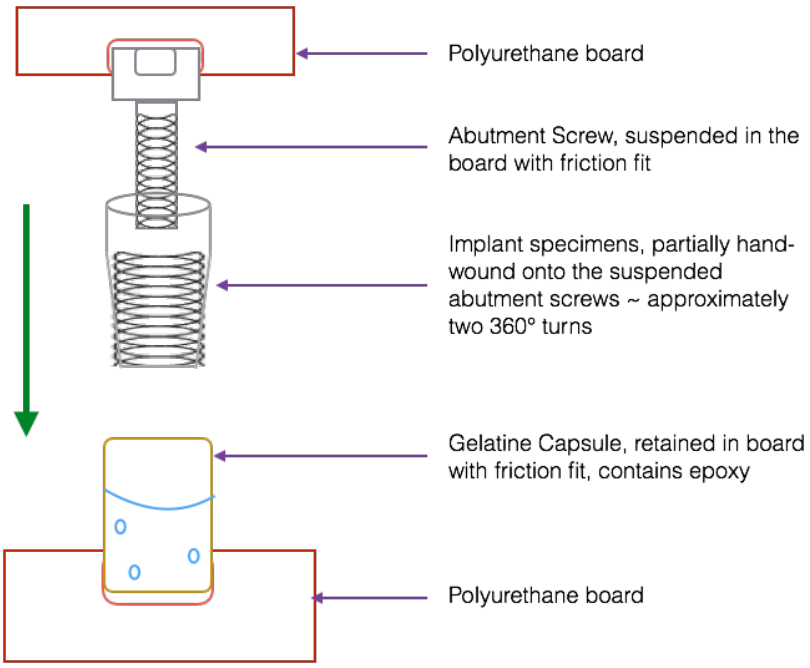


Figure 15 (c): Schematic diagram of specimen preparation/mounting protocol. Suspended implants are lowered into gelatin capsule containing epoxy and allowed to set over 48 hours.

Gelatin capsules were filled approximately two-thirds by volume with a clear epoxy resin (resin base/hardener as a 2:1 ratio). A polyurethane spacer was placed above the gelatin capsule slab, before the abutment/implant arrangement was then lowered into place. Implant fixtures were then suspended in the resin-containing gelatin capsules and allowed to set over the following 48 hours. This process was repeated for each of the fourteen implant specimens required for the study, visualised in Figure 15(c).

3.2.2 Installing and setting the specimens for scanning

With implant specimens now rigidly retained within the epoxy resin, it was then possible for rigid fixation of the respective abutments, both generic and proprietary. Each specimen was taken to a bench vice within the dental laboratory of the Adelaide Dental Hospital and hand tightened securely as per figure 16. Both proprietary and generic abutments were placed onto the fixtures one time only and secured with the Neoss Crystaloc abutments screws described in chapter 3.1.3.

Each abutment screw was torqued to $32Ncm^{-1}$ as per manufacturer guidelines, using the Neoss torque wrench (figure 17).

Figure 16: *Neoss ProActive implant secured rigidly with epoxy resin in gelatin capsule. Specimen has been held in place with bench vice here, awaiting abutment insertion*

Figure 17 (a) and (b): *Installation of the Ti NeoLink Mono abutment (Neoss Implants, North Herefordshire, UK). Firstly secured by hand (a) using the driver only. The epoxy resin/gelatin capsule holds the fixture rigidly in place without damaging the implant itself during a torqueing procedure (b).*

3.3 Specimen testing

3.3.1 Microtomography

A SkyScan1076 computed microtomography scanner (figure 1) was used to scan the prepared implant-abutment specimens at the commercial facility, Adelaide Microscopy (Adelaide, South Australia). Specimens, already mounted within the epoxy resin containing gelatin capsules, were placed approximately vertically within the sample holder, with the aim that the scanning beam was similarly approximately perpendicular to the specimen. Each sample was scanned at 9μm resolution with a source voltage of 100kV, 100μA x-ray beam current and using a 1mm aluminium filter.

Output files were in the Tag Image File Format (TIFF) and relatively large, with each slice in the order of 16MB.

3.3.2 Pre-Processing of raw scan data

Scan data for 14 samples were generated from the SkyScan1076 in a TIFF file format. Each sample generated a series of these files representing a unique cross section through the specimen itself as per the process described in Chapter 2.10. Reconstruction of these relatively large files was conducted using the Windows-based programs, NRecon and DataViewer (Bruker microCT, Kontich, Belgium), which was able to generate a compatible file format (BMP) for analysis in Avizo 9.0 (FEI, Oregon, USA).

3.3.3 Qualitative analysis

Qualitative analysis was achieved via the program, Avizo 9.0 (FEI, Oregon, USA). Through using this software, it was possible to volumetrically render three-dimensional models of each sample with the ability to manipulate them in space. Virtual slices were taken in transverse and coronal sections to specifically view the main area of interest – the implant/abutment interface.

Given that the abutment specimens in the proprietary cohort differed in their shape and structure to those of the generic cohort, it was necessary to identify similarities for the purposes of qualitative comparison.

The proprietary group abutments make contact with the implant fixture in two discreet places only: horizontally, on the flat surface at the top of the implant fixture; and vertically at the level of the implant's internal hexagon.

These proprietary abutments are designed with a cylinder that passes, without contact, into the coronal third of the implant fixture. As described in chapter 3.1.2 this cylinder is the foundation for three anti-rotational lugs that do indeed contact and engage the internal hexagon of the implant fixture, albeit in a novel way. When these lugs are engaged with the implant body, they undergo a unique deformation that is characteristic for each individual lug/implant complex. It was at this level and others (Figure 18) that qualitative analyses were made, as well as the position where the abutment makes horizontal contact with the superior fixture surface.

The vertical contact between the proprietary abutments was described earlier and shown in two-dimensions with the deformation lugs contacting the implant's internal hexagon in the mesh schematic of Figure 7. To examine these lugs at a closer level, it is only the furthest extension of these lugs that has a point contact with the implant, with this occurring laterally on the internal hexagon. This point contact extends vertically for the entire length of the anti-rotation deformation lug, providing an increased surface area of contact, with the flatter outer aspect of the lug not making contact with the implant at all.

For the generic specimens, we knew that they lacked any version of a deformation lug, having simply a hexagon-shaped geometry for their abutment connection as described in Chapter 3.1.2. It was unknown how this hexagon would interact with the internal surface of the implant's internal hexagon, and certainly one of the aims of the study. Conversely, from observation prior to connection it was known that the generic abutments had a flat horizontal component that was due to contact the top of the implant fixture.

For the purposes of this analysis, the same three planes outlined for proprietary group specimens in figure 18 were used for generic group specimens. This enabled determination of similarities and differences that the two abutment designs possessed when connecting to an implant of an identical design.

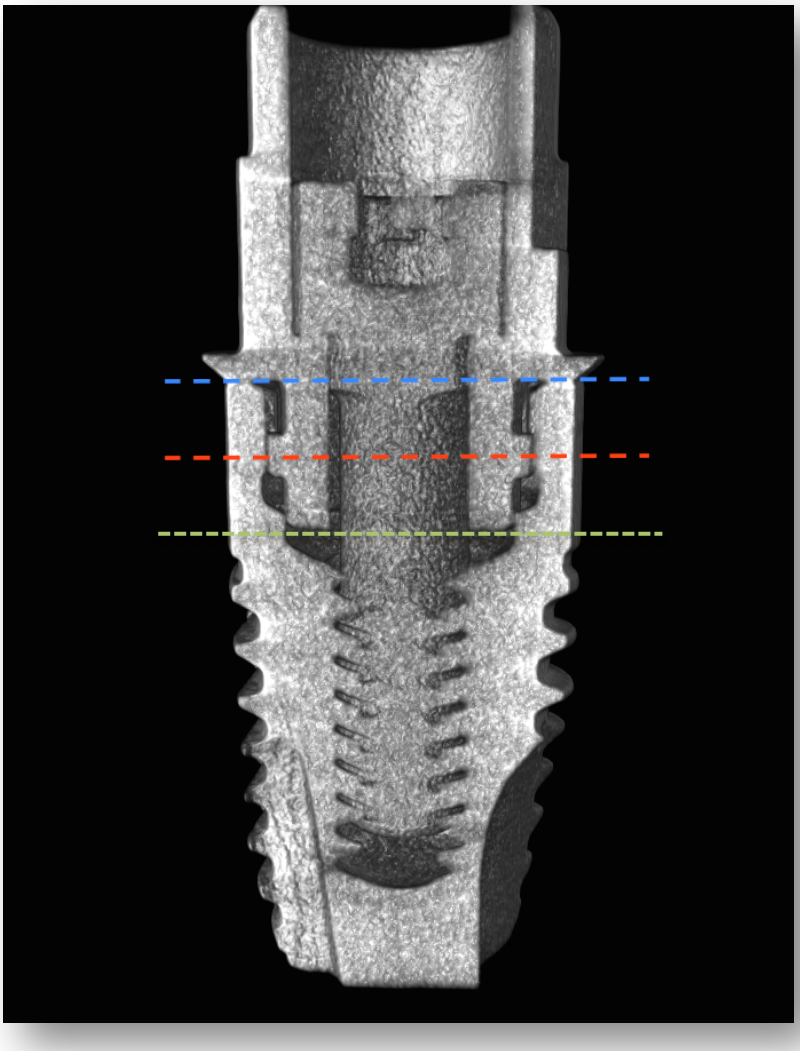


Figure 18 (a): *Screenshot taken with Avizo 9.0 software during qualitative analysis. Utilising proprietary group specimens in (a), coloured lines indicate three positions of interest that have subsequently been used to examine the generic group specimens. A blue line indicates position where abutment contacts the fixture with a horizontal orientation. The red line indicates where the abutment is contacting the fixture in a vertical orientation. The green line indicates an area of interest at the lowest point of the abutment in the fixture.*

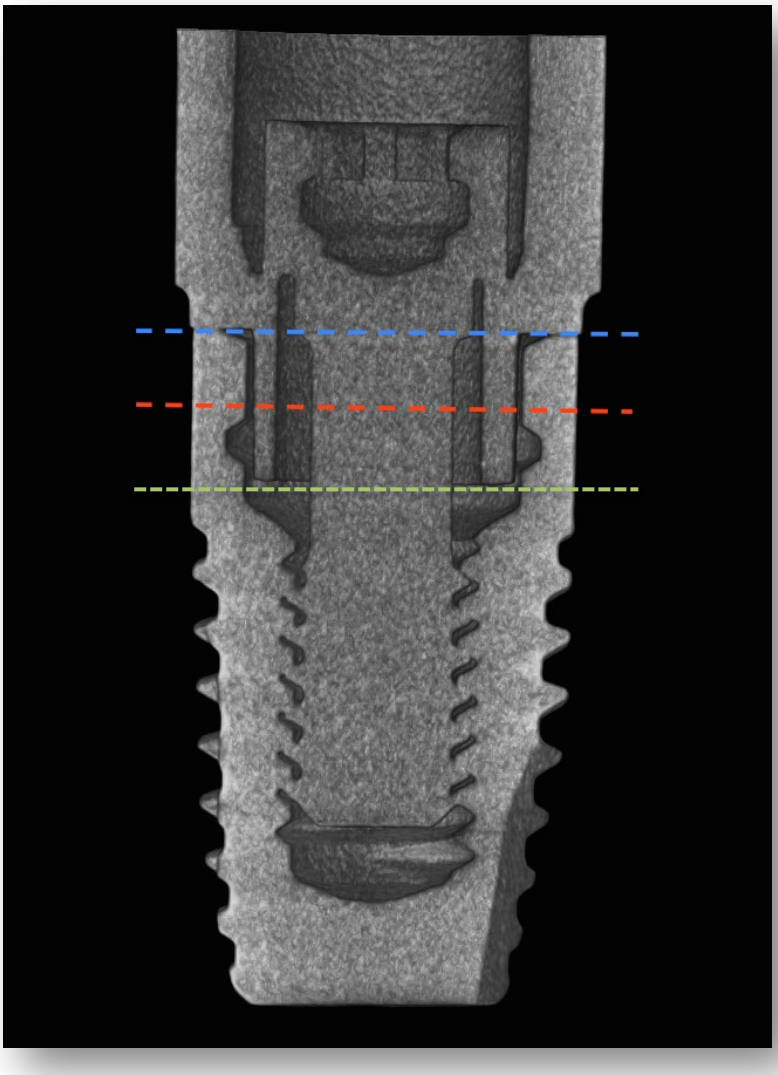


Figure 18 (b): *Screenshot taken with Avizo 9.0 software during qualitative analysis, utilising generic group specimens in 18 (b). The same coloured lines at the equivalent positions three positions of interest shown in 18(a) are shown here.*

Chapter 4 Results

The study's general aim to compare quantitatively the proprietary and generic dental implant-abutment connection using computerised microtomography was met. Following scanning with the Micro-CT, three-dimensional volume rendering was conducted using the Avizo 9.0 software package for each of the sample's own datasets as per the study methods. These were non-destructively observed in their entirety, both externally and internally across the two observational groups.

Using these three-dimensional digitally-rendered models, the three specific study aims were also met; allowing a non-destructive observation of the internal aspects of the Neoss ProActive implant, in addition to an assessment of the similarities and differences of the connection of both proprietary and generic abutments to the implant itself.

To satisfy the study aims and for illustrative purposes. Screenshots were taken with the Avizo 9.0 software (these screenshots are provided in the appendix chapter). For each specimen within the proprietary group and generic group, the following screenshots were obtained:

- Two external views of each specimen
- Three cross-sectional views, observed at the three levels described in Figure 18: high, midpoint and low
- Three coronal views, taken as slices when the specimen is vertically positioned, moving from external and superficial, through the specimen

and out the other side. These slices were characterised as: anterior slice, midpoint slice and posterior slice.

These views were chosen to best represent the gross changes that were observed of the interaction between abutment and fixture at varying heights and depths of the connection. It was felt that these screenshot views provided the best viewpoint to assess the similarities and differences between the proprietary and generic abutment-connections, as per the specific study aims. Any slice that could be taken superior or inferior to those in the cross-sectional views was considered to be not relevant to the observations and aims of the study. Similarly, with respect to the coronal views, the three orientations selected best captured the spatial interaction of the abutment to the fixture, which varied amongst the samples due primarily to the rotational orientation of each specimen. While an attempt at standardizing the vertical aspect of the specimens was conducted in Chapter 3.2.1, the methodology was not concerned with the rotational differences that each specimen displayed. In fact, as there were differences in rotational positioning, it gave an ability to observe the difference specimens with a fresh perspective each time, lending itself to satisfying the general aim of qualitative assessment of the entire connection across all samples. Given that the observation for a coronal screenshot simply required that each specimen needed to be orientated vertically, the resulting images that were obtained did indeed present variations that were different amongst the specimens of each group because of the rotational orientation variance.

It was judged by the author that a wider variation in images would be generated this way and thus an increased chance of observing an interesting interaction between the fixture and the abutment if the rotational orientation of the specimens was random. These results, as they pertain to the study aims will be discussed in the following sections- external views, cross-sectional views and coronal views, with reference to the screenshots contained within Appendix A:.

External views

Proprietary group and generic group specimens were observed externally. At the magnification observed with these screenshots, no visible gaps between abutment and fixture were found for the proprietary group specimens. A continuous, homogeneous connection was observed between the implant and proprietary abutment. Through use of the digital zoom function in the Avizo software on these views, it was still not possible to find distinguishable space observed between the two components. In fact the only discernable way to establish that there was a connection, was via the shape transition from the vertical external wall of the implant fixture to the angled base of the NeoLink proprietary abutment.

For the generic group specimens, only one of the external views of the seven specimens demonstrated no gap at the abutment-fixture interface (specimen 2, figure 105), with the additional external view of this specimen showing a gap and even a view of the internal screw (specimen 2, figure 104). In both of these screenshots for specimen 2, the junction between the two parts was visible with

the generic abutment seeming to be wider than the fixture to some degree. The remaining six specimens in the generic group all demonstrated an observable gap between the abutment and fixture, with some more marked than others (specimen 5, figure 137).

From a relevance point of view, the upper aspects of the generic group specimens were removed from the scan data to reduce the file size for post-scan processing. The data from the upper portion of the abutment was not considered relevant as it fell outside the areas indicated in Figure 18.

Cross-sectional views

These cross sectional images illustrated the unique connection of the Neoss proprietary abutment to the internal fixture structures, seen in proprietary group specimens. These Micro-CT images were seen as comparable images to the mesh schematic drawing from Figure 7. The six internal orientations of the fixture's internal hexagon are demonstrated well at the 'high' and 'midpoint' slices for all specimens in this group. The 'low slice' for proprietary group specimens was not dissimilar to the 'high' slice as both regions of the abutment lack engaging components at this level. As such, the abutment is becoming more cylindrical at the 'low slice' level and becoming more hexagonal at the 'high slice' level. The lack of contact between the abutment and the abutment cylinder at either of these levels possibly improves the passivity of fit.

At the midpoint slice for each of the proprietary group specimens, the characteristic feature of the Neolink abutment was easily observed: three alternating non-engaging hexagonal corners with three engaging lugs extending from the cylindrical aspect of the abutment and contacting the inner wall of the implant hexagon with lateral terminal projections (figure 19). This feature allows the abutment to meet the fixture at the previously described six discreet point contacts (two for each lug process), deforming the abutment itself at these points in a characteristic fashion that is unique to that individual lug process and individual fixture hexagon position.

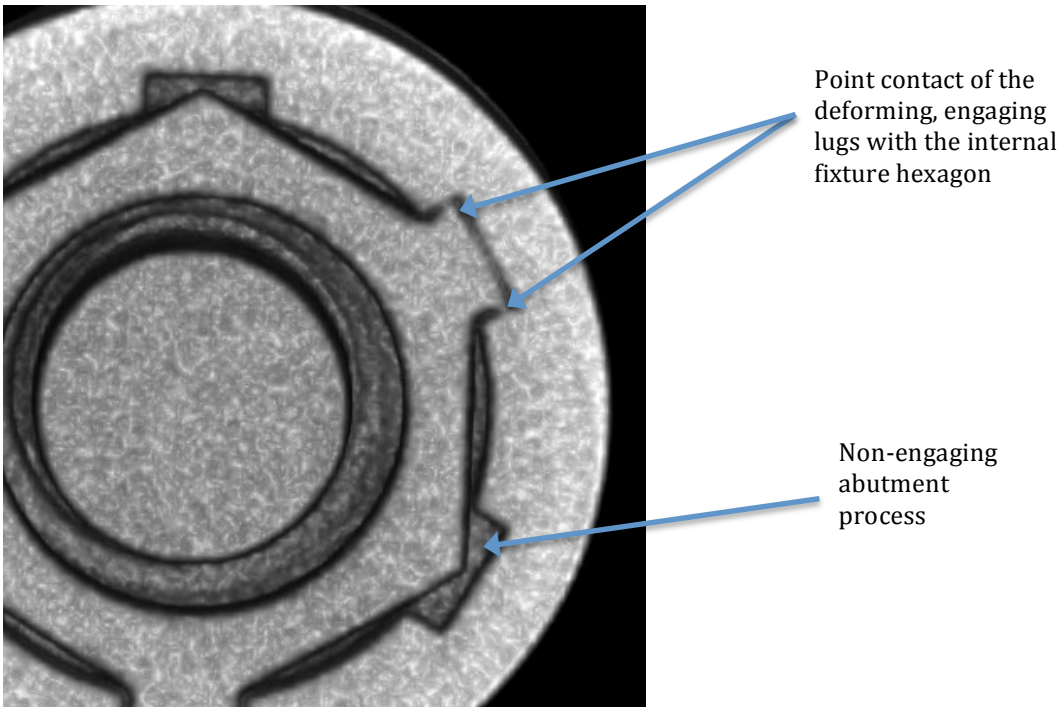


Figure 19: *Unique characteristics of the Neoss titanium NeoLink Mono attached to Neoss ProActive implant, as seen in cross-section (midpoint slice)*

The proprietary group specimens each demonstrated identical contact points in cross sectional views. The software was not able to demonstrate the extent to

which deformation of the lugs occurred, instead contact was observed through the merging of the two surfaces with no intervening black line. This was consistent at all zoom levels possible with the Avizo 9.0 software.

Generic group specimens demonstrated much wider observational variation overall. These abutments were designed to engage with the implant fixture using a different method due to proprietary copyrights and trademarks. As can be seen in figure 20, the abutments themselves have a different geometry compared with the Neoss hexagon. While still contacting the fixture at point contacts, this occurs at twelve points (two for each hexagon extension), rather than the six points of the proprietary abutments. In addition, the abutment is making contact with the fixture on its inner wall, rather than within the internal hexagon.

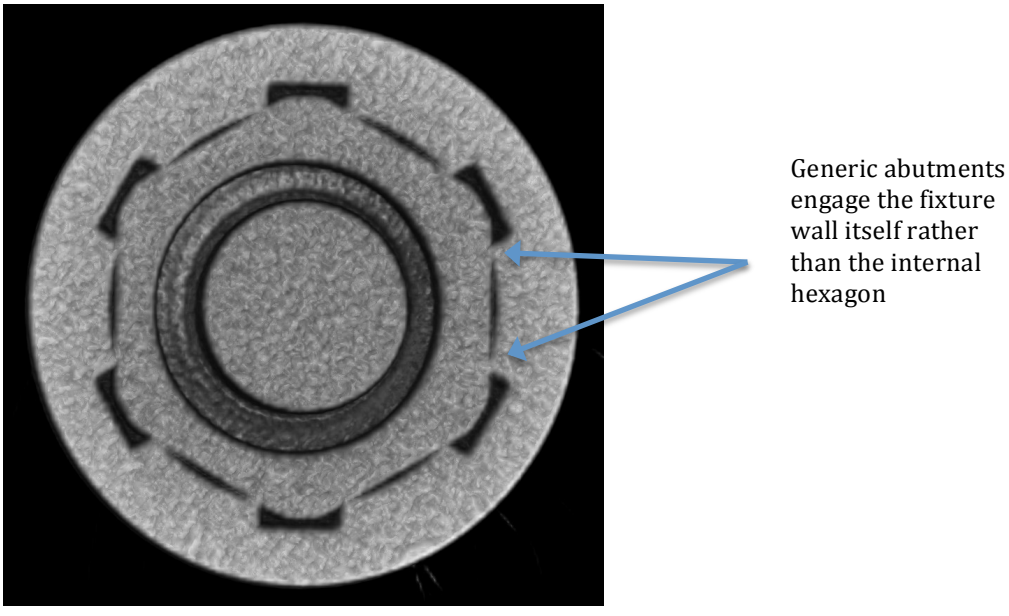


Figure 20: Generic titanium abutment attached to Neoss ProActive implant, as seen in cross-section

While there are these clear differences between the proprietary and generic abutments at this cross sectional level, the function of this aspect of the abutment is to maintain an anti-rotational fit. At a cross-sectional level, both abutments are successful in this, however they are achieved with different designs.

The six additional contact points that generic group specimens have with the internal fixture increase the chance that there will be an interference that prevents passive seating. However, assuming precision and accuracy in their manufacture, the additional contact points that these specimens possess may present no disadvantage to passivity whatsoever.

Coronal views

Coronal views were taken of the proprietary group and generic group specimens when they were vertically positioned. Given that there were points of interest at different depths, virtual slices through specimens, were taken in three arbitrary planes: an 'anterior' slice, an approximate 'mid-point' slice, and a 'posterior' slice. These slices accounted for all inter-group variability that arose due to differences in rotational orientation.

The coronal view provided the best opportunity to observe the horizontal interface at the abutment-fixture connection. Within the resolution limitations provided by the Avizo software, proprietary group specimens consistently demonstrated even contact between the horizontal processes of the NeoLink Mono abutment and the most superior component of the implant fixture. At no point during examination

of the coronal views was there a gap discernable for proprietary group specimens at this superior, horizontal interface.

By comparison, there was much greater variation amongst generic group specimens. Each of the generic group specimens demonstrated a vertical gap at the horizontal interface that varied in observable size depending on the position of the vertical slice (anterior, mid-point or posterior) and randomization of the rotational orientation of the respective specimens.

Observing the vertical process of the respective abutments as they descended into the fixture demonstrated the points of contact that specimens showed in the transverse views. For proprietary group specimens this was apparent in several images with the lug process of the NeoLink Mono abutment contacting the fixture wall, when this wall was at its narrowest. At all other positions and virtual slices, there was no observable contact with proprietary group specimens aside from: the horizontal fixture-abutment interface and the characteristic Neoss anti-rotational lugs (for example, figures 85, 86 and 87).

Generic group specimens appeared to have a longer and more frequent contact between the vertical abutment process and the fixture wall. In addition, this contact appeared to occur when the fixture wall was at its thickest, which compares well with the transverse views, demonstrating that the abutment is engaging with the internal fixture wall, rather than the internal hexagon as per proprietary group specimens (for example, figures 112, 113).

Further differences were noted between the two groups on coronal view, most critically being the perceived length of the abutments' vertical process. As described, proprietary group specimens had two distinct areas of contact with the fixtures; the length of the vertical abutment was observed to not extend further into the implant such that additional contact would occur. In all proprietary group coronal views, a space was observed between the most inferior aspect of the vertical abutment process and the beveled inner wall of the fixture, thus ensuring no premature contact inside the implant body prior to seating with the horizontal process of the abutment. As described, generic group specimens demonstrated inconsistency with the marginal seating of the horizontal process of the abutment, with variations in marginal gap observed. This coincided with an increased length of the vertical abutment process, whereby contact between this vertical process and the internal aspect of the implant was observed in all generic group specimens at some point in the coronal views (for example, figure 122). By inference, this contact is another point of difference between the two abutment types and demonstrates the aforementioned premature contact. The broader this contact is across the coronal slices for generic group specimens, the more marked the abutment-fixture marginal gap appears to be.

Further evidence that abutment geometry may be contributing to marginal gap is noted when examining the abutment screw and its position within the internal fixture thread. All proprietary group specimens complete their seating when the most inferior portion of the screw thread is housed in the second-last internal

thread (for example, figure 95). For generic group specimens however, the abutment screw is not able to make it beyond the third-last internal thread (for example, figure 112). This demonstrates a notable difference in terms of componentry fit. However, it must be noted that differences in the geometry of the abutment screw-head position are possible, with a thicker platform design for the screw heads themselves suspected in the generic abutments compared to the proprietary abutments.

Following these observations, an attempt was made to determine the reason for misfit. Authors elected to unscrew the abutment screw of one of the generic group specimens (specimen 4) that clearly demonstrated an unseated abutment-fixture connection *(*figures 128, 129, 130, 134, 135 and 136); the purpose of this being to undertake an analysis of these particular components when not in function. Clinical photographs (Canon EOS 60D, Canon EF 100mm f/2.8L Macro IS USM) were taken of the process to document the observations and have been included in the results chapter as an additional focus. These photographs clearly show a gap between the components when in their macroscopic state used for the scanning process (figure 22). Removal of the abutment, allowed observation of the anti-rotational aspect of the generic group specimen's abutment and the internal arrangement of the implant fixture. A clear 'scuffmark' is easily seen at the base of the fixtures' internal hexagon at the position where the abutment has contacted the implant fixture and been compressed via the pre-load applied to the abutment screw (figure 23). A corresponding rounding of the hexagon is also noted on the abutment hexagon itself (figure 24).

The length of the abutment internal hexagon was reduced to half its length with laboratory burs and polished (figure 25). The abutment was then torqued back into place with the Neoss torque wrench to the same manufacturer specification - $32Ncm^{-1}$. Macroscopically, there was an observable difference in the way the abutment and fixture connected and felt upon torqueing, with no gap being readily observed following the abutment adjustment, as recorded by the SLR camera (figure 26).

Subsequently, the adjusted specimen was rescanned as per the original modality with newly generated scan data utilized for analysis by Avizo 9.0 software. Images have again been included in the results chapter, but clearly show a difference in the seating of this abutment specimen.

The scuffmark noted in figure 23 was evident in the images obtained through the re-scanning process as observed in figure 32. Six of these marks are noted in the areas where the abutment made premature contact with the fixture. The transition from high cross-sectional slice to low-slice underlines the differences that a shorter abutment process creates, with no abutment processes noted in the low-point slice compared to all other images generated for generic group specimens.

The coronal views (figures 33, 34 and 35), provide a greater opportunity for observing this contrast. At the abutment-fixture interface, the absence of a dark-line separating the two surfaces provides the best evidence that they are now in

fact contacting. In other words, within the resolution limitation provided by the scanning process, these components are contacting better than any of the other specimens did within generic group. Equally, the abutment process that was adjusted certainly appears shorter in these scans and a sizeable distance away from the lower fixture wall. Interestingly, the apparent final resting position of the abutment screw tip is different to the images of specimen 4 pre-adjustment (figures 134, 135, 136). This difference could be attributed to the different length of the vertical abutment process, but there is possibly more to consider.

If we refer back to the original specimens prior to the generic abutment adjustment, we can see some relative differences. In Figure 21 the platform that makes contact with the abutment screw head is a different relative thickness in the proprietary abutments compared to the generic abutments. This shorter platform on proprietary abutments, coupled with no detectable marginal gap, allows the screw apex to reach 'deeper' into the implant fixture. The thicker platform in the generic specimen however, coupled with the marginal gap in this image (Figure 21) gives rise to a relative difference of at least one to two threads in the apical engagement of the abutment screws.

Once the abutment was adjusted the marginal gap was removed (figures 33, 34 and 35), however the thickness of the abutment screw platform within the generic abutment remained the same. The final apical resting position of the abutment screw in this adjusted generic specimen was still short of the proprietary specimens. The clinical relevance of such a finding however is yet to be

established. The additional feature in Figure 33 is indicated by the blue arrows at the implant-abutment interface. The arrows are indicating the previously suspected finding that the generic abutment is slightly wider than the fixture itself, creating an unfavourable platform mismatch. It has been shown that shifting the platform to smaller diameter abutments than the implant platform reduces the amount of periimplant marginal bone loss[116,117]. In the current situation, with a wider implant abutment than implant platform, loss of periimplant marginal bone loss at the shoulder of a mismatched implant abutment connection can be associated with further biological complications that may trigger inflammatory events with potential for further progress of periimplant disease[116-118].

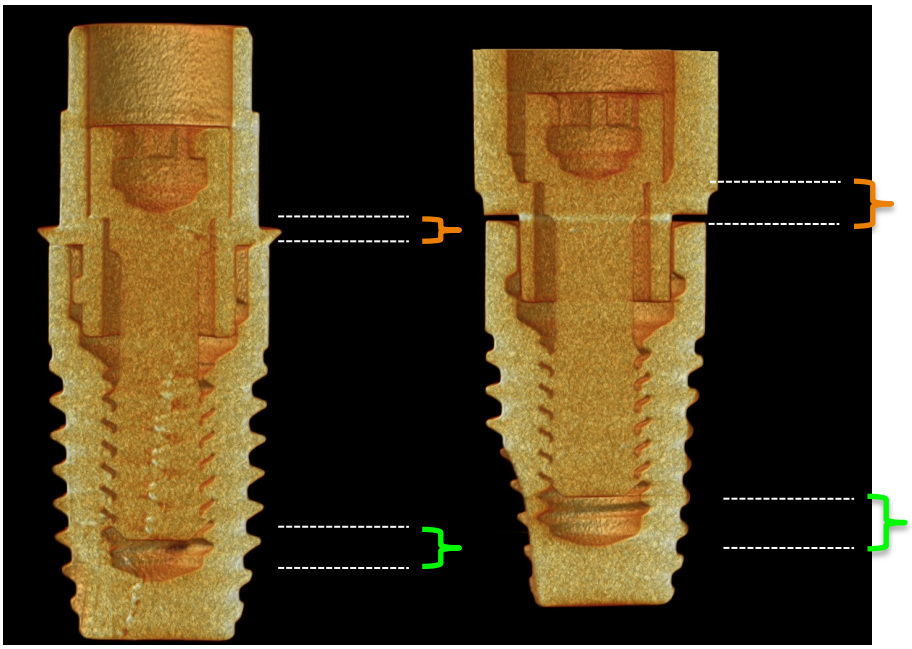


Figure 21: *A relative comparison of the screw head platform thicknesses between a proprietary specimen (left) and an unadjusted generic specimen (right). These thicknesses are depicted with an orange bracket, whereas the impact is noted in the apical area of the abutment screw (green bracket).*

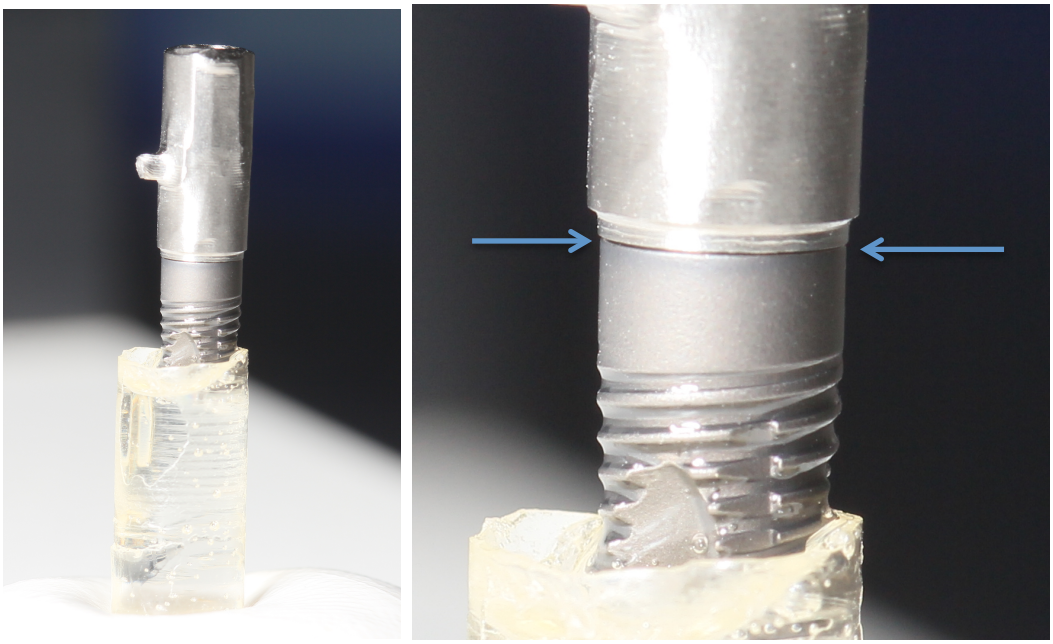


Figure 22: Specimen 4: Generic titanium abutment attached to Neoss ProActive implant. Note the observable gap at the abutment-implant interface as indicated by the blue arrows.

Figure 23: Specimen 4: Generic titanium abutment attached to Neoss ProActive implant. "Scuff marks" are evident on the internal aspects of the implant as indicated by the blue arrows

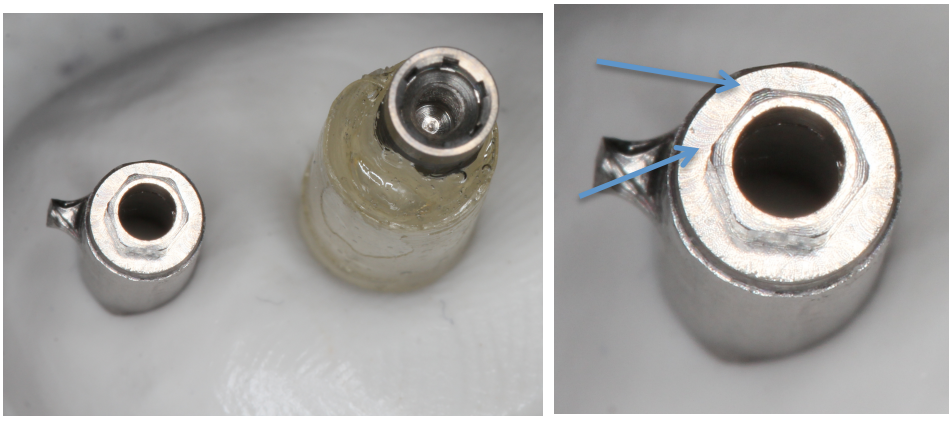


Figure 24: Specimen 4: Generic titanium abutment. A definite 'rounding' of the abutment's hexagon is noted, as indicated by the blue arrows.

Figure 25: Specimen 4: Generic titanium abutment. The abutment had approximately half of its hexagon height cut off and polished with laboratory discs

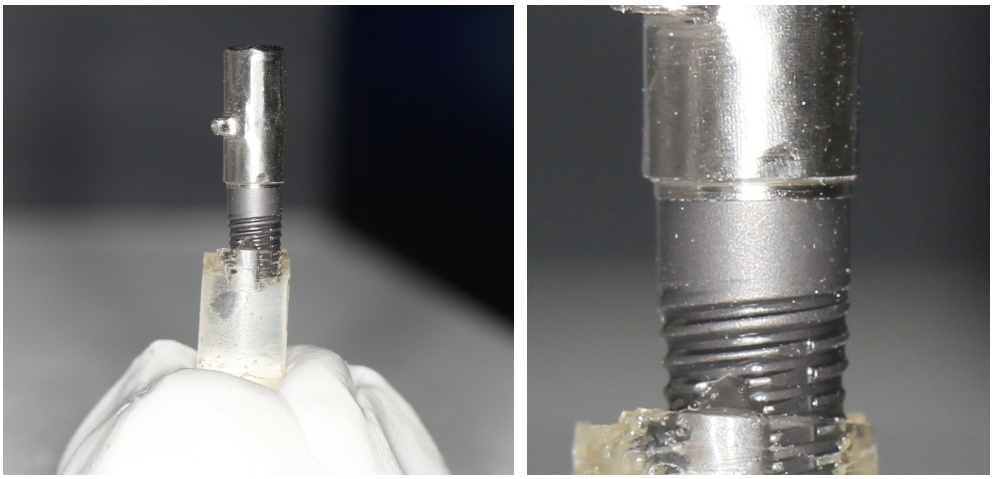


Figure 26: Specimen 4: Generic titanium abutment, reattached and torqued to its original implant fixture following the adjustment to the abutment's hexagon, note the change in the marginal gap.

Specimen 4 – adjusted abutment

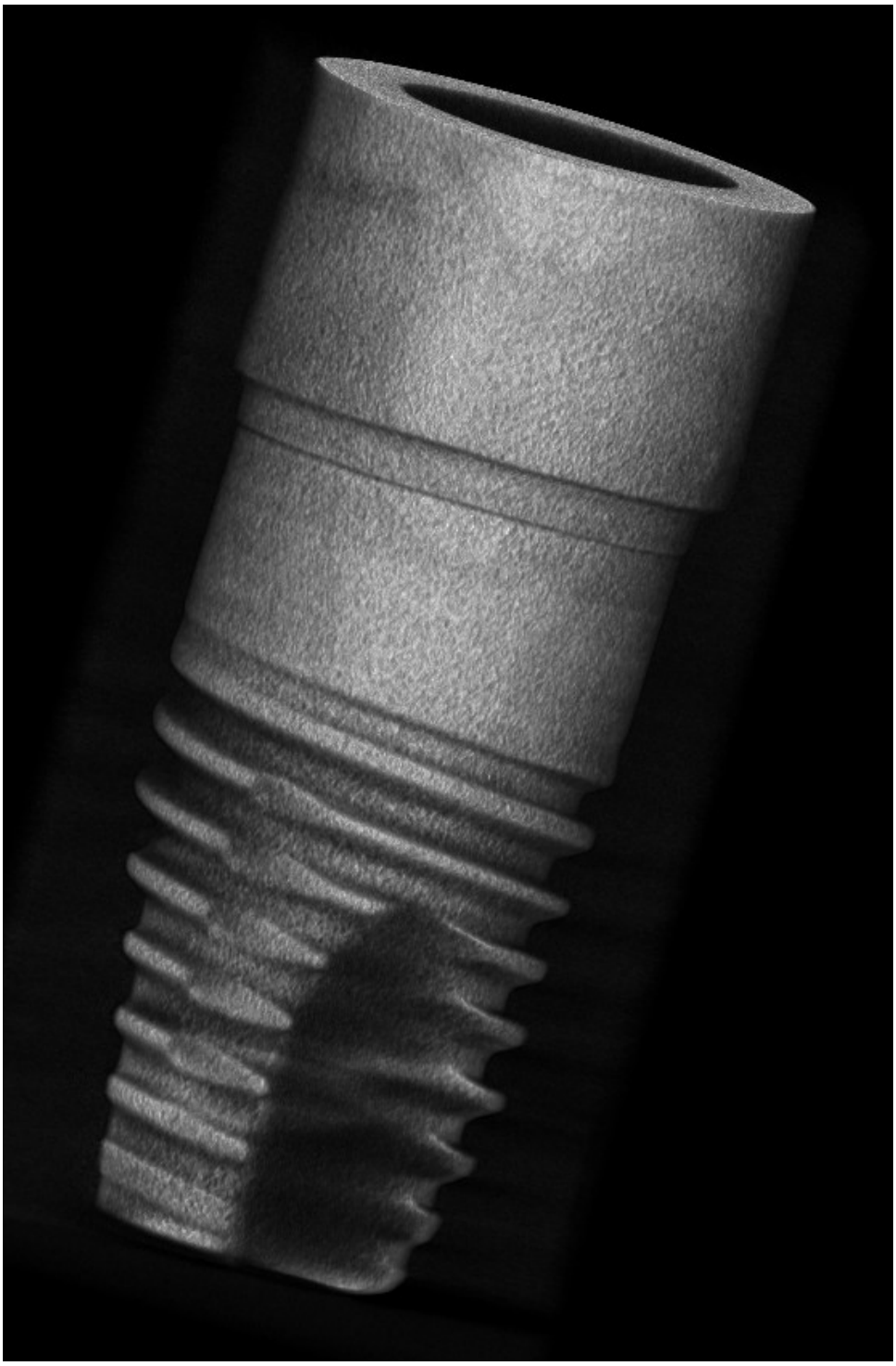


Figure 27: Specimen 4: External View 1 – The adjusted generic titanium abutment attached to Neoss ProActive implant

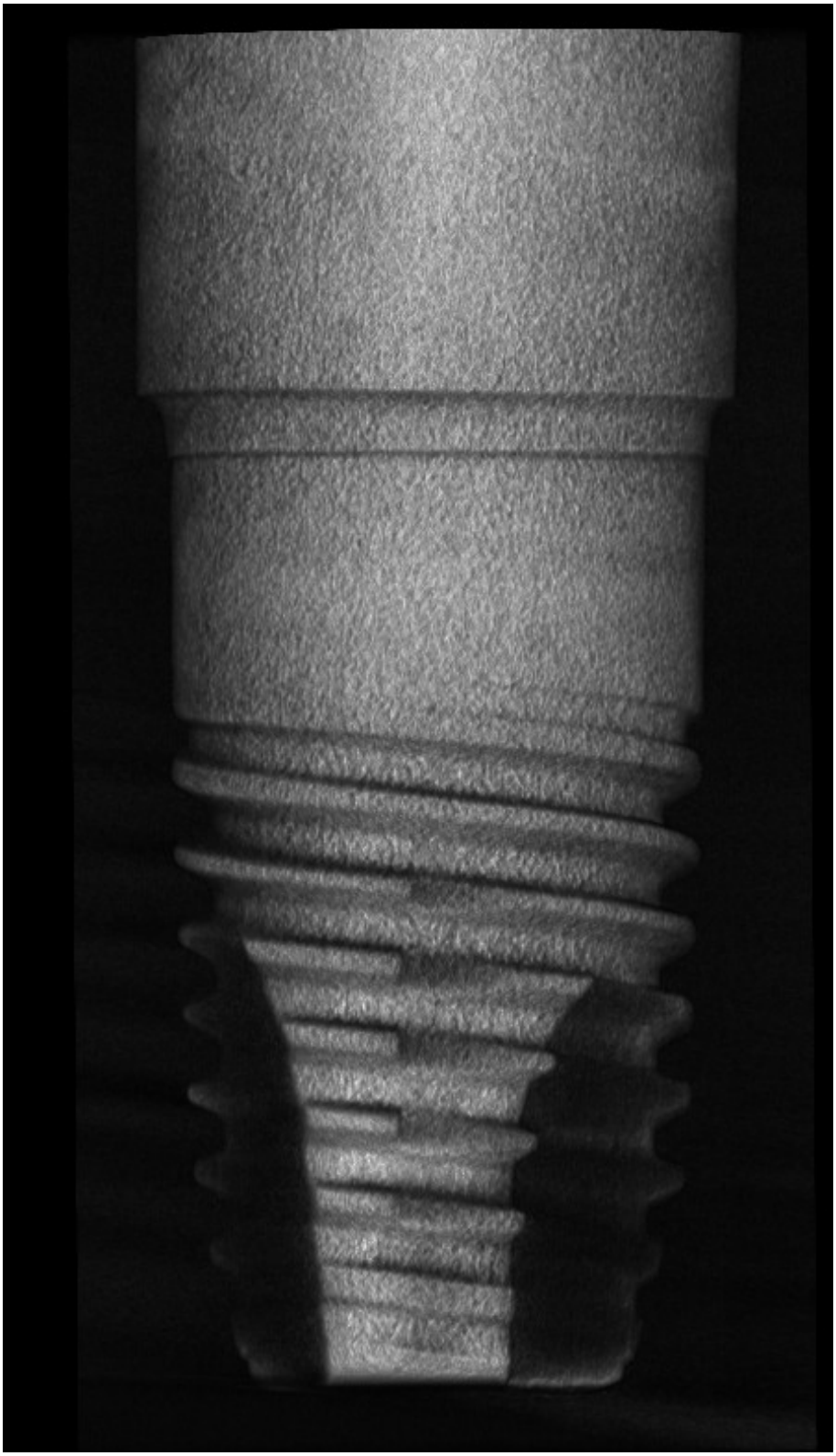


Figure 28: *Specimen 4: External View 2 – The adjusted generic titanium abutment attached to Neoss ProActive implant*

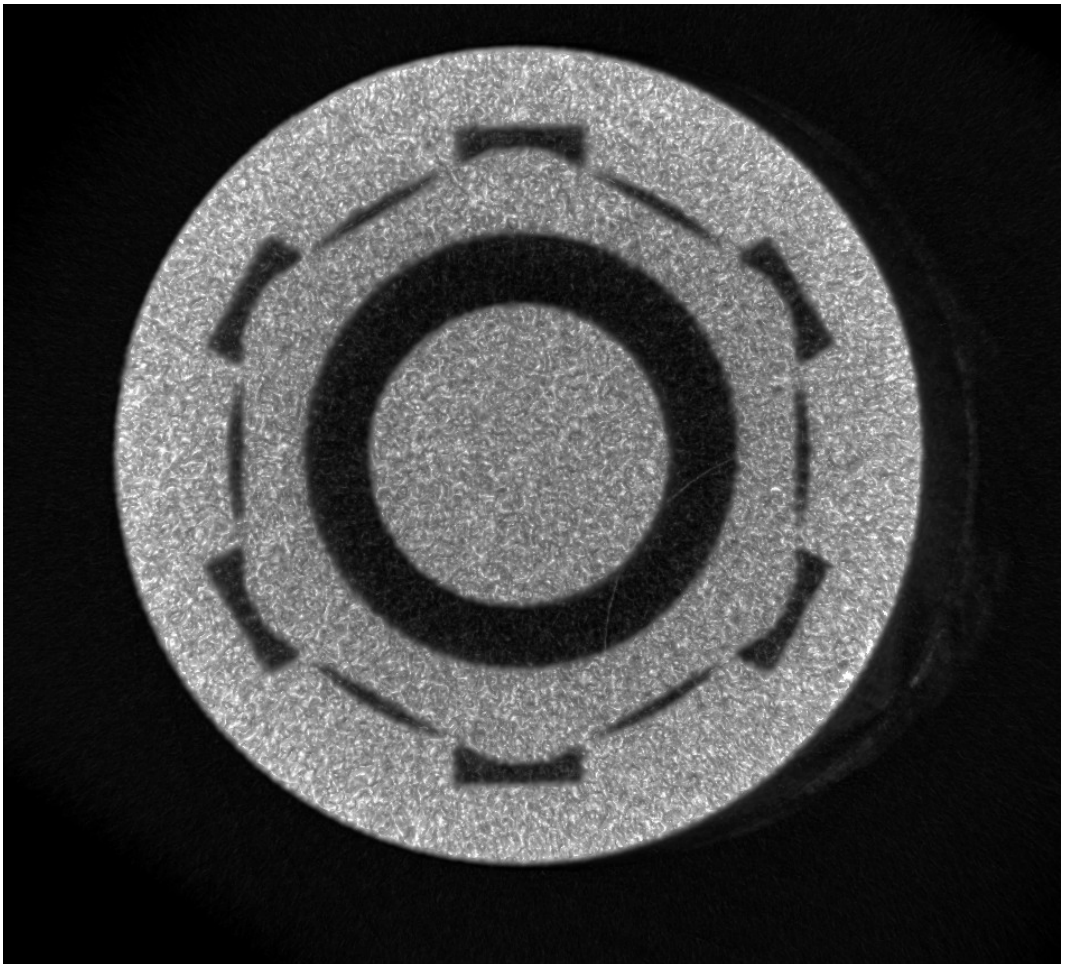


Figure 29: Specimen 4: Cross sectional transverse View 1 (high slice) – adjusted generic titanium abutment attached to Neoss ProActive implant

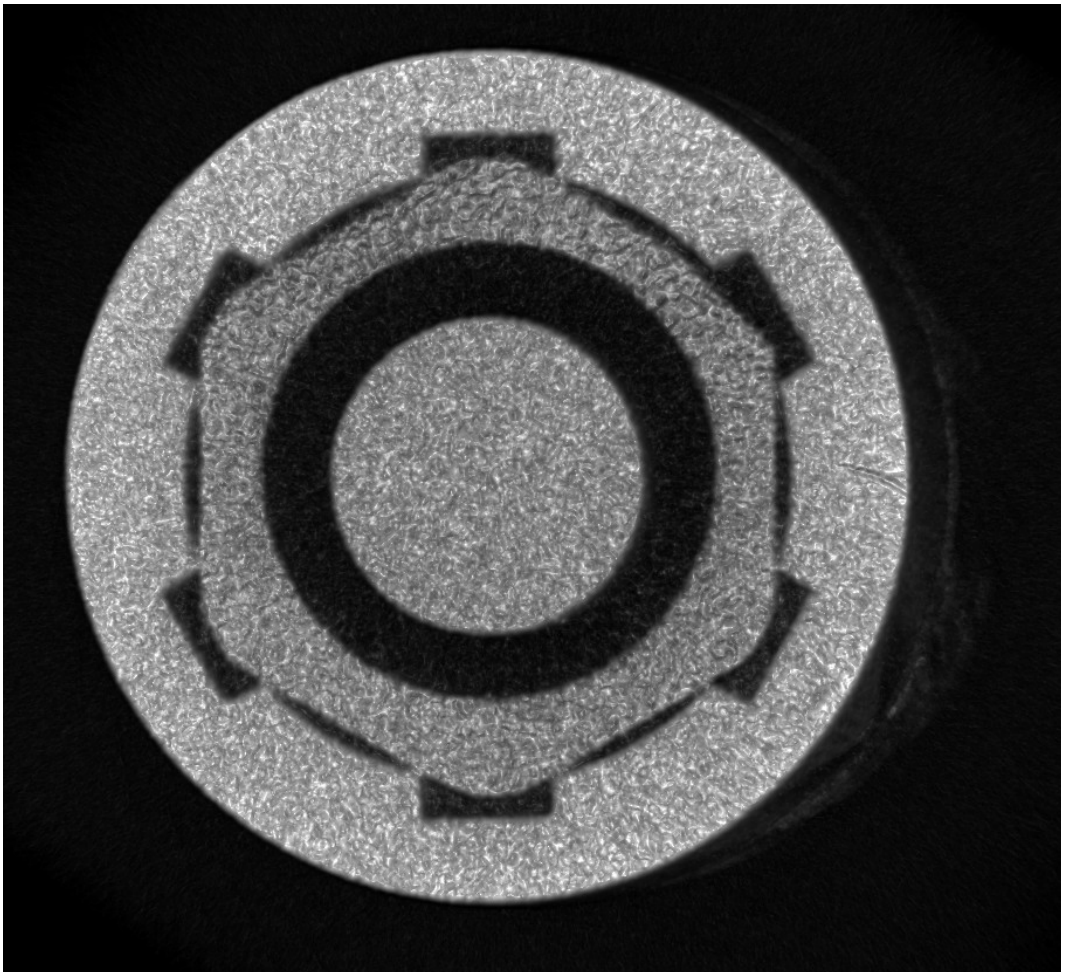


Figure 30: *Specimen 4: Cross sectional transverse View 2 (midpoint slice) – adjusted generic titanium abutment attached to Neoss ProActive implant*

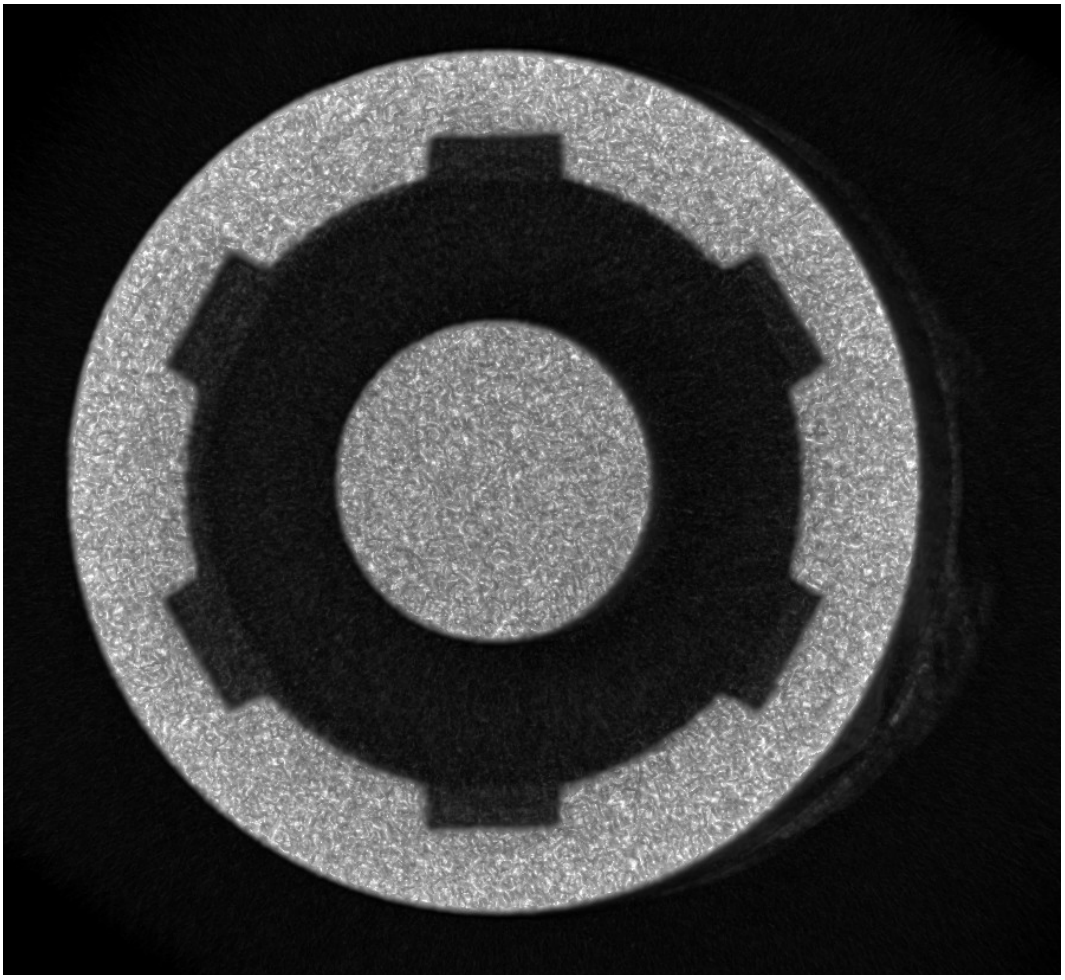


Figure 31: *Specimen 4: Cross sectional transverse View 3 (low slice) – adjusted generic titanium abutment attached to Neoss ProActive implant*

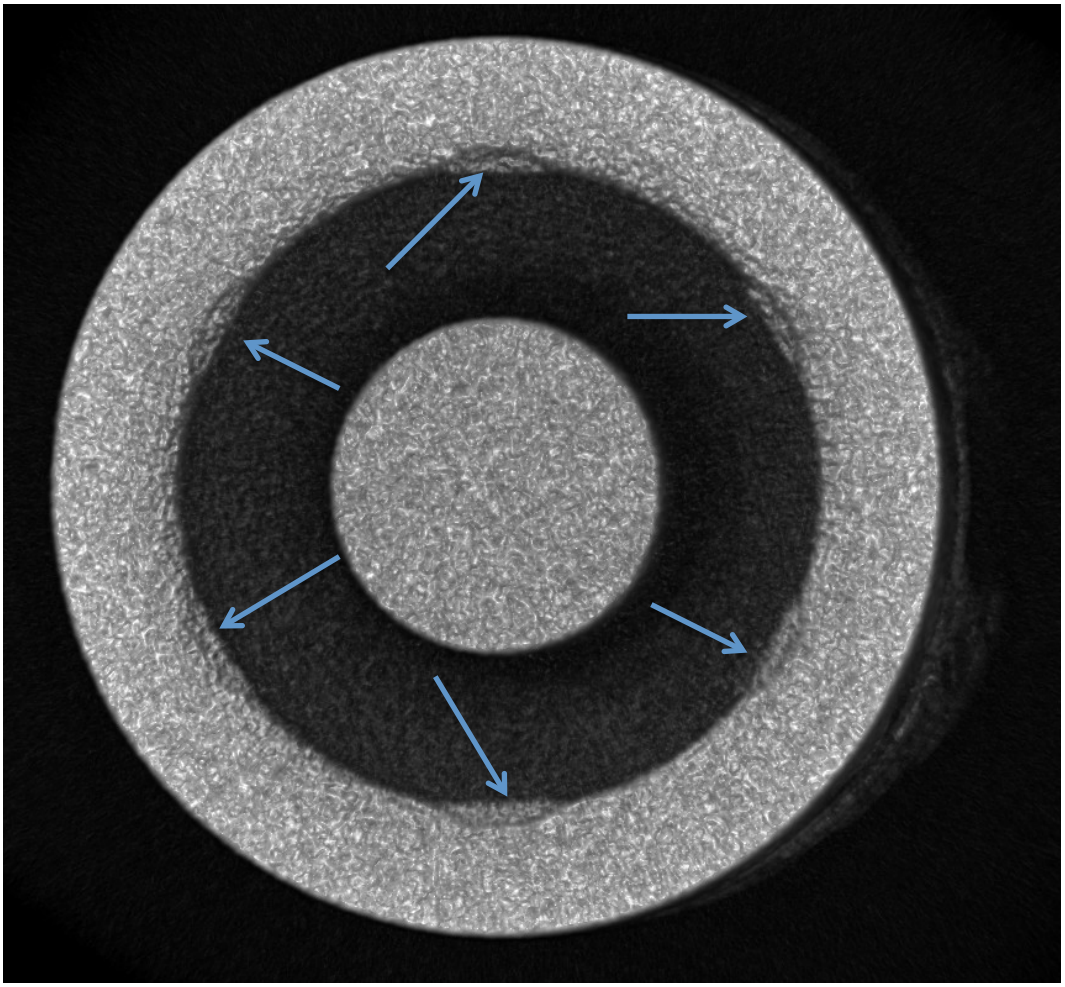


Figure 32: *Specimen 4: Cross sectional transverse View 4 (extra low slice) – adjusted generic titanium abutment attached to Neoss ProActive implant. Note the markings where previously the vertical abutment process marked the internal aspect of the fixture.*

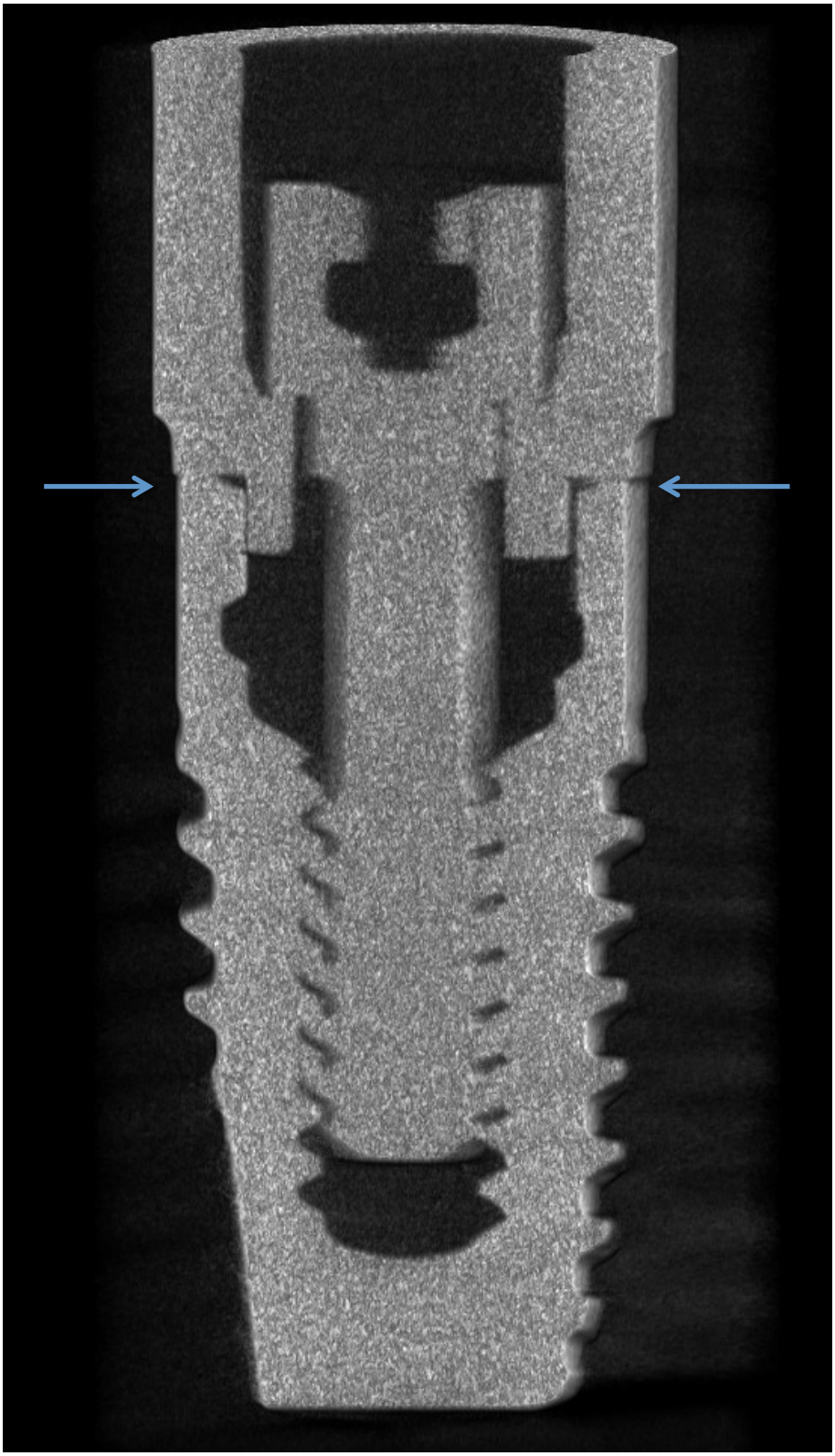


Figure 33: *Specimen 4: Coronal View 1 (anterior slice) – adjusted generic titanium abutment attached to Neoss ProActive implant. The arrow indicates where the abutment is wider than the fixture, but no marginal gap is detected.*

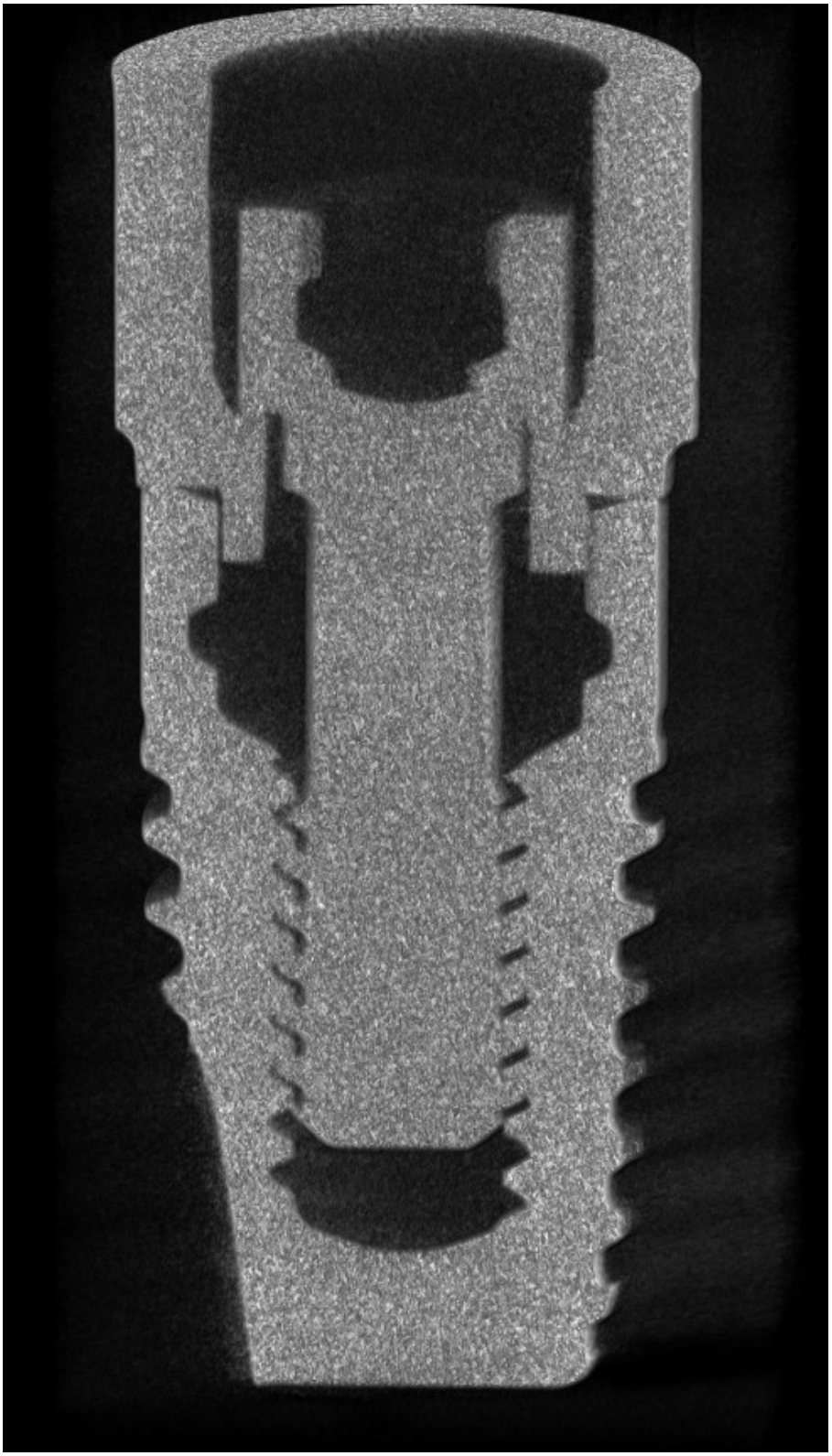


Figure 34: *Specimen 4: Coronal View 2 (midpoint slice) – adjusted generic titanium abutment attached to Neoss ProActive implant*

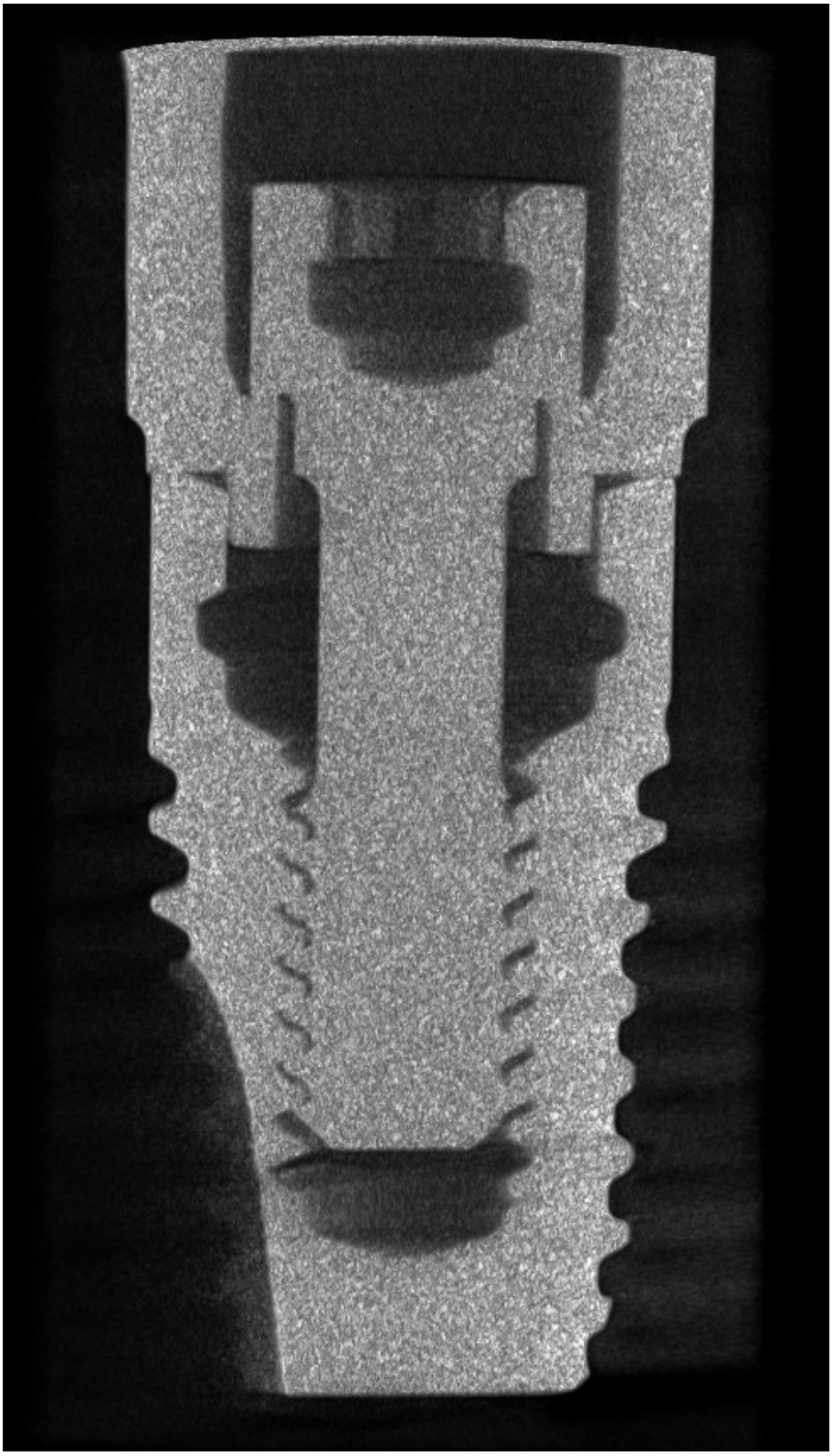


Figure 35: *Specimen 4: Coronal View 3 (posterior slice) – adjusted generic titanium abutment attached to Neoss ProActive implant*

Chapter 5 Discussion

A qualitative analysis of the abutment-fixture connection and geometry of the specimens in the proprietary and generic groups has been performed. Our results demonstrated considerable differences between the two groups – with each utilising a different design to facilitate implant-abutment connection. Ultimately however, in spite of their differing designs, they are largely successful in their goal of attaching to and maintaining an aspect of anti-rotation.

However, in terms of ideal fit, the words of Alves da Cunha and coworkers resonate: "with any misfit, either vertical or horizontal…. (it is) able to apply a load to the implant assembly and the surrounding bone". Clinically, this places at risk both the mechanical and biological components of the fixture-abutment system. It is thus important to identify why there is misfit in the first place.

The major finding of this investigation was the appearance and magnitude of the marginal gap between generic abutments and proprietary implant fixtures. Using the images and scan data, it appeared that this gap varied in magnitude across the specimens, with some showing a larger marginal gap than others.

This variation however depended largely on how the specimens were positioned during the computer analysis with Avizo 9.0. As mentioned in the methodology, it was intentionally decided that a randomization of the rotational angulation would be used for these specimens. This was an attempt to derive a greater spread of images that could offer insight into the geometry of the respective connections.

However, this also produced images that appeared to show wider or larger gaps at the marginal interface for some specimens within the generic group, compared to others. In reality however, as the virtual slices taken through the specimens were done for qualitative purposes, it was decided that the rotational orientation of the specimens not be standardised either within or between the two groups. This difference in rotational orientation gave rise to coronal images that represented a random sampling of distribution of marginal gaps. Potentially, a rotational variation of 60° about the central axis could produce a considerably different coronal slice image as we approach the specimen from a different starting perspective.

A macroscopic observation of the specimens from the proprietary and generic groups was conducted at time of specimen preparation. Compared with proprietary specimens, the generic group abutments were less passive during insertion/attachment to the fixtures. As demonstrated, generic group abutment specimens had twice as many positions of contact within the fixture compared with proprietary group specimens. By inference, depending on the path of insertion and in-built tolerances of the abutment design, there may be more points of contact during the seating of generic group abutments than proprietary group. This would occur simply by virtue that more metal is contacting at any given time for the generic group abutments. The tactile experience noted during specimen preparation of the two groups reflected this, with the proprietary group abutment echoing the Neoss descriptor as being a “press-fit” connection- these specimens permitted a relative wide path of insertion angle; conversely, the generic group

abutments behaved as more of a “friction-fit” thus restricting it to a relative vertical path of insertion.

The generics manufacturer, Stoneglass Industries, decided upon the construction method for the generic abutments. The request to utilise a proprietary implant replica was a methodology the company had used previously to construct generic abutments of other proprietary implant connections. The imaging and qualitative analysis conducted in this study identifies a marginal discrepancy for all generic group abutment specimens. The decision to re-scan one of these specimens (generic 4) following adjustment to the hexagonal process of the abutment, was an attempt to highlight the suspected design element causing the abutment-fixture misfit. Simply put, the abutments were too long, prematurely bottoming-out when contacting the inner surface of the fixtures. The difference between the Neoss replica and Neoss ProActive implant was not investigated during this study, however it is quite clear from our results that there is relative difference.

Clinically, the unique characteristic deformation lugs that Neoss utilises with its “press-fit” abutment design are only made possible if there are no adverse changes made to the abutment during fabrication of an implant restoration. This could only occur if the replica used to make the restoration does not prematurely distort the deformation lugs prior during prosthesis fabrication, prior to clinical restoration delivery. As a result, Neoss replicas are designed to contact the abutment relatively passively by not engaging the anti-rotation deformation lugs, and providing increased space inside the replica to prevent the premature

activation of the deformation lugs. Any internal geometry copied from this replica design is going to be different therefore from the implant fixture itself. Copying this relatively passive geometry of the replica is going to absolutely produce a wider and deeper generic abutment. Our results attest to this, whereby generic group abutments from a tactile viewpoint felt less passive on insert and scan data showed their vertical process to be too long. This lead to subsequently poorly adapted implant-abutment connections, with open marginal gaps, when compared to the proprietary group specimens.

Implant manufacturers produce componentry to internal proprietary standards and tolerances. It is generally relatively unknown how rigorous this testing can be within companies, however often clinical data are used by these companies to position their products in the marketplace as being more desirable over another. Similarly, generic manufacturers seem to follow a similar pattern, with a large focus on clinical outcomes rather than rigorous scientific research.

Within the limitations of this study, it can be deduced that it would have been more appropriate to utilise an implant fixture itself, rather than a less expensive replica to reverse engineer the generic abutments. Once again, this was a decision made by from the outset of the study to more accurately recreate an everyday clinical situation. While some implant manufacturers might have little or no difference between their implants and replicas, intentionally or otherwise, the unique connection that Neoss has designed only works appropriately if there are differences between the fixture and replica. Knowing this, it would be

recommended that generic manufacturers treat each connection as a unique fingerprint attributed to each implant manufacturer, carefully understanding the geometry and structure of a connection prior to reverse engineering. Certainly, if that is the restorative option of choice, and a clinician needs or decides that the use of a generic component for in the restorative workflow is necessary, then a generic abutment needs to be reverse engineered from the most precise point of origin: an implant proper, rather than an implant replica.

From a precision point of view however, a number of authors have described the pitfalls of an imperfect fit[1,2,65,119]. It stands to reason that the fit between two parts made within the same corporate framework is going to be superior to a reverse engineered generic component. With that in mind and coupled with the results of the present study, it begs the question as to what would motivate a clinician to use generic componentry to restore dental implants.

Expanding upon the reasons clinicians might make during the fabrication process of dental prostheses, anecdotal evidence can be gleaned from a conversation with any restorative clinician, past or present. The challenges encountered on a daily basis in restorative dental practice are wide and varied; patient care, costs of practicing and the concept of diminishing time are all key issues for today's restorative clinician. Indeed, the influence of local and global economic conditions has been reported in the context of dental training. With the costs of a dental education continuing to rise, it has been reported that graduating dentists are seeking a higher income, something which they feel is needed by the graduate

to maintain a standard of living comparable with those of previous dental school graduates[120]. It is therefore possible that the consequences of such a mindset may influence a restorative clinician to make clinical decisions on the basis of financial gain, rather than what is perceived to be in the patients' best interest dentally- certainly this is a contentious point, however the financial reality of rising costs at several junctions in the dental continuum will ultimately have an influence.

Proprietary Restorative Componentry		**Generic Restorative Componentry**	
Custom Impression Tray and Impression Material	~$70	Custom Impression Tray and Impression Material	~$70
Impression Coping	~$90	Impression Coping	~$45
Implant Replica	~$55	Implant Replica	~$18
Proprietary Titanium Universal Stock Abutment (and screw)	~$140	Generic Titanium Universal Stock Abutment (and screw)	~$45
Milled Zirconia crown with veneering porcelain (implant manufacturer's own milling centre)	~$220	Milled Zirconia crown with veneering porcelain (generic milling centre)	~$120
Additional cementation	~$65	Additional cementation	~$65
TOTAL	**~$640**		**~$293**

*The torque-limiting device has been separated from the total calculation on the assumption that a restorative clinician likely possesses this instrument prior to commencing with the restoration of implants. These are also considered a one time only expense.

Torque Limiting Device	**~$1400**	**Torque limiting device**	**~$900**

Table 3: Restoration of a dental implant with a Single Implant Crown Comparative costs (AUD$)

When considering the comparative costs to a restorative dentist tasked with restoring a dental implant with a single crown, the range between the least and most expensive can be stark. The differences are dependent upon the choices both between and within implant manufacturers own catalogues and the alternatives offered by generics. To illustrate this, an outline of costs has been provided (in Table 3) as a contemporary estimate of incurred fabrication costs for the restoration of an implant with a single crown in Australia. It must be stated however that this is but one method of fabrication and comprises a workflow that commences with an analogue impression. For the purposes of this example, a custom impression tray has been selected (with an approximate cost of $50 for fabrication in Australia by a commercial laboratory), with the impression material estimated to be approximately $20 per arch, if a popular local polyether impression material were to be used (Impregum™ Soft, 3M Oral Care, St. Paul, Minnesota). Similarly, the design for the prosthesis is only one of many possible fabrication methodologies and relies upon an additional laboratory step of cementing components together prior to delivery to the dentist. This design is characterised by a stock metallic interface between the implant and the crown, in this instance titanium, that acts as a base for a machined ceramic crown, in this instance zirconia. The crown is designed and fabricated with an abutment screw channel already in place, having been milled in this manner by the milling centre prior to laboratory delivery. Additionally, with respect to the fitting surface, corresponding matrix geometry at the base of the zirconia crown has been designed with CAD software (with several types available, the choice is dependent upon the machinery being used) prior to the milling process such that it

will have the ability to encompass the patrix geometry of the titanium abutment. Once the fit and occlusion of the respective components has been assessed, the laboratory will attach the abutment to the implant replica on the master model using the prescribed laboratory abutment screw. It is recommended by the vast majority of implant companies to not use clinical screws for laboratory processes. Remembering to carefully block out the screw channel within the crown, the crown is then cemented onto the stock titanium abutment with a definitive laboratory luting cement of a desired type and allowed to set or be light cured. Once the cement has sufficiently set, the crown with the newly luted abutment is removed via unwinding of the abutment screw, assessed for cement excess and duly polished for intra-oral delivery.

This crown fabrication methodology was chosen as an example as it is relatively straightforward to separate the various components of the restoration into their constituent parts for cost comparison. As can be seen, there are certainly differences in costs, however there are a number of similarly priced components irrespective of the proprietary or generic workflow. One of the key factors within our present study was the different abutment design produced by the generic manufacturers, Stoneglass Industries, following a reverse engineering process using a proprietary implant laboratory replica. When comparing the costs (estimated in table 3) between proprietary and generic workflow however, there is certainly a difference, with the proprietary component being slightly more than twice the price. Similarly, the impression coping was estimated to be twice as expensive for a proprietary component as compared to a generic. Given the

findings of this study, there exists an aspect of doubt when it comes to the behavior of these components during an impression. If a proprietary workflow is selected, then within the available componentry there is proprietary knowledge of the inbuilt tolerances of the components used, hence the impression coping fits as it is intended within the implant and then subsequently during the connection to the proprietary replica. By contrast, the generic impression coping and by inference the generic implant replica have been designed to fit one another with as much accuracy and precision that the CNC milling machine they were created by, allows. Given that a sole generic manufacturer would usually provide an impression coping and replica for a specific case, it could be assumed that the tolerance of fit between the two components would in of itself be of a proprietary nature within the generic companies own manufacturing process- hence the fit would be predictable and expected by the manufacturer. However there are two potential instances where error may enter the work flow: once the impression coping is attached to the implant, and once the impression coping is subsequently attached to the replica following an impression. In both situations, there is greater potential for rotational misfit[3] rather than vertical misfit, whereby reduced tolerances below proprietary manufacturers intentions may permit rotation of impression posts within or upon an implant by some fraction of degrees. This would be more likely of an outcome versus vertical misfit due to the ability for a flat surface to be produced with greater ease than the series of complementary surfaces required for the various connective processes of an implant – internal or external. This comment is in spite of the findings of the present study; where rotational (internal hexagon prematurely engaging) and vertical misfit both

occurred as a result of selecting a technically unsuitable starting point for reverse engineering an abutment. With the Neoss connection being such a unique interaction between implant and abutment, the use of an implant replica was an inappropriate choice on the part of the generics manufacturer as a point for reverse engineering the generic abutment. As described, an implant itself would have functioned as a more appropriate starting point to derive the required dimensions needed for a more precise generic abutment.

The connection of a generic component to a proprietary one represents an unknown quantity, when considering the integrity of such a connection. On a clinical level, it has been reported that absolute passive fit is not possible[38], begging the question as to how a component manufactured upon machinery without proprietary knowledge of the desirable and safe tolerances of another component could have a chance of fitting in the way it has been intended. In addition, the machinery used during the manufacturing process of generic componentry, some of which has been described in this particular study, will be different depending upon the manufacturer. There will be inherent differences between and within the machines themselves: age, size, number of milling axes, maintenance, quality control, quality assurance, insulation, even the dimensions and isolation of the room that the machine is contained within such that disruption of the machining process by environmental factors is not inadvertently permitted. Once again though in an abstract sense, does this level of precision have any clinical relevance?

With these thoughts in mind, the gains made via cost reduction of utilising generic impression copings and implant replicas to generate a master model seem secondary, given the potential for errors and potential clinical sequelae, whether due to rotational misfit or otherwise.

Further differences in the cost of items exist between the torque limiting devices, the very instruments used to impart the preload upon the various abutment screws used within restorative apparatus. As far as the calculation presented in Table 3, the comparative costs for the respective torque-limiting devices is displayed as a separate component from the total calculation. The reason being that it is assumed a restorative clinician has purchased this instrument as a one-off set up expense from the outset and would not necessarily need to be factored into the ongoing restoration of dental implants. It is not the intention of the current study to pass comment on the nature of torque limiting devices, however there are certainly calibration tools available for the purposes of assessing and registering the effectiveness of a torque limiting device in its function of imparting preload of a desired magnitude upon restorative screws. The estimated price of a proprietary manufactured torque limiting device versus a generic device is an issue that may motivate the purchase of one over the other in terms of ownership or utilisation within clinical practice, however as stated, there is need for appropriate calibration to ensure the accuracy of torque readings when using the device of choice. One of the main advantages of the generic torque limiting devices though, is often they are sold as a bundle with a multitude of interchangeable drivers, this is certainly useful in practices that restore more than one type of implant system,

giving flexibility to not only restore many implant systems but also render assistance to patients that may present to a practice with unknown componentry.

Perhaps the most significant component listed however is the interface between implant and crown – the titanium stock abutment. In the estimates there are two quite different costs provided (~$140 for proprietary vs ~$45 for generic), with the relatively low generic cost offering some suggestion as to how competitive this aspect of implant dentistry has become. It also adds to the restorative methodology debate, raising the issue of how costs have influenced the way restorative clinicians choose to restore implants. The process by which this example has been described: using a CADCAM, veneered, ceramic crown luted to a titanium base in the laboratory, and the screw retained in the mouth is a relatively recent methodology made more attractive by the decreasing costs associated with CADCAM fabrication of crown and bridge restorations. Previous methodologies made use of casting and the lost wax technique to fabricate custom abutments with either precious or non-precious metallic alloys. If the additional cost of using precious casting alloy wasn't enough to discourage price-sensitive restorative clinicians, then the additional time taken to complete the casting stages for custom abutment fabrication, might very well be. Therefore there is an increased attraction to utilising an off-the shelf, stock-abutment that theoretically all that is needed is to mill a crown to fit the abutment shape and cement this on. The additional bonus that this stock abutment is of proprietary-origin provides an increased surety at the critical implant abutment interface; the component has

been specifically designed by the implant company itself, who are then in control of the known internal tolerances.

The disparity between the proprietary and generic prices however is a concern, however anecdotally this has been reducing in recent years with proprietary stock abutments previously priced as high as proprietary customised CAD/CAM abutments. At least in the form of the various universal stock-abutments available across the various systems, we now find these to be significantly cheaper than what they once were. In reducing the cost barrier, implant companies would seem to be hoping for restorative clinicians to be more inclined to utilise a proprietary implant connection, thus reducing the risk of potential complications arising from connecting a generic part to an implant.

With cementation of a milled crown being the same cost irrespective of proprietary or generic, the last stage in the fabrication process to show a difference is the manufacturing of the milled crown. There can be high variability in the fabrication costs of these components from a generic perspective, generally this is the result of how convenient it has become for clinicians to mill their own restorations within the dental practice setting, something that was previously only available to dental laboratories. The ability to produce a crown through a CADCAM pathway is entirely dependent upon the software being used to drive the machinery. While there are various implant companies with a production capacity in the restorative aspect of their business (Straumann Cares, Nobel Procera, Astra Atlantis) there are many more that exist through having so-called

trusted connections with milling centres. In this way, implant companies maintain a production pathway that customers can rely upon; being assured that any prostheses that is produced, has been through a process that has been assessed and maintained to industrial standards of quality control.

Given the heterogeneous nature of generic manufacturers, it is often impossible to know the scope of their respective quality control and quality assurance programs. However, certainly there exist pathways for generic manufacturers to establish themselves as credible alternatives through alignment with independent local or international accreditation bodies such as ISO (International Organization for Standardization, Switzerland), NATA (National Association of Testing Authorities, Australia) or the TGA (Therapeutic Goods Administration, Australia) to name but a few.

The estimated price differential between the proprietary and generic CADCAM zirconia crown is not small, with the proprietary estimated as being almost twice the cost. However, in the restorative scenario posed as previously described these prostheses are being cemented onto metallic stock-abutments. There is therefore the potential, within reason, for the cement to make up for any perceived or real inaccuracies that have been created during the milling process. Depending upon the precision of the machine used during the manufacturing process, as well as the accuracy of the CAM data used to design the crown/abutment interface, it may be possible to create accurate negative representations of the abutment extension with sufficient tolerance built in for cementation, such that seating the matrix of

the crown onto the patrix of the abutment is a passive, yet stable connection that can ultimately be sealed and stabilised by the laboratory cementation process. At this time, there is lack of rigorous scientific evidence for the clinical use of these prostheses, however they serve the purpose as an example of economic comparisons between proprietary and generic single implant crown reconstructions.

Another such motivation for clinicians to utilise generic components in the restorative workflow is to supplement perceived shortcomings of a proprietary catalogue. Until recently, there had been relatively few implant companies capable of supplying a proprietary restorative solution to correct labial emergence of restorative screws, when there had been a clinical desire for a retrievable, one piece, screw retained abutment. In situations when the implant fixture angulation resulted in a labial emergence of the retentive screw access hole, either a comparatively unaesthetic restoration may be needed to disguise the screw access or the clinician previously had to utilise a cement-retained crown or transverse/palatal screw retention into a separate abutment. A number of generic manufacturers therefore were able to meet the needs of the restorative clinician by being creative enough to supply a restorative alternative that met the needs of the market: angulated screw access via the alteration of abutment screw heads and screw driver shape changes.

Despite Nobel Biocare launching their proprietary NobelProcera ASC abutment (Angulated Screw Channel) in February 2014 with a new driver tool (the

Omnigrip), there were no other similar products available from other major implant manufacturers at the time. This tool differed from Nobel Biocare's previous abutment driver tool (the Multigrip) in that it was able to engage the novel, more concave screw head design with friction grip up to 30 degrees from the axial direction of the screw itself. With this design, clinicians were able to restore anterior implants possessing labial inclination using a single screw retained crown – screw access being able to emerge from a more desirable palatal direction, rather than labially.

One Australian generic component manufacturer, Osteon Medical, launched an angled screw solution in October 2013. Known as the Bi-axial collection®, their solution was offered to address the restorative deficiencies of several implant systems on the market at the time, having the flexibility to restore both external and internal connections with optimal positioning of the implant frames to be produced without the need for expensive abutments, redirecting screw access by up to 30 degrees, making it both financially and aesthetically more attractive. The systems available shortly after launching this product included: AstraTech/Dentsply Implants; Ankylos; Biomet 3i; Bio Horizons; MIS; Nobel Biocare; Neoss; Osstem; Southern; Straumann; Swiss Plus and Zimmer.

Osteon Medical maintains a patent on their design, although, as previously described a similar restorative solution was launched by Nobel Biocare in early 2014 for their NobelReplace® Conical Connection implant system. The key difference between the two manufacturers though, Osteon Medical and Nobel

Biocare, is the flexibility that the former can offer restorative clinicians. Where Nobel Biocare offered their ASC option only for single CADCAM Zirconia abutments, Osteon Medical offered their Bi-axial connection for all contemporary implant connections in the Nobel Biocare catalogue, in addition to the long list of systems already described.

This gap in the availability of novel components, needed by restorative clinicians to restore their implants of choice with the most modern techniques available is a significant hurdle. It is certainly a key factor in the decision making process for clinicians when electing to utilise generic or proprietary componentry – the at times, inflexibility of proprietary restorative workflows.

With increasing pressure from generic manufacturers, implant companies are being forced to innovate in order to maintain, or increase, their market share. Nobel Biocare's ASC abutment is one example of this, but the lack of additional availability across their other product lines has allowed the emergence of faster-acting generic companies to enter the space.

Despite the variability amongst regional legislation, it would seem that multi-national corporate entities such as implant companies are held to more rigorous and exacting legislative control than manufacturers of generic componentry as it pertains to the production and sale of devices for use in the human body. One reason for this may relate to the stark differences in the legal definition of what

constitutes a medical device versus the more open interpretation of what defines a custom-made medical device.

In Australia, the fabrication, supply and use of medical devices in the human body falls under the *Therapeutic Goods (Medical Devices) Regulations Act 2002* and is overseen by the Therapeutic Goods Administration (TGA)[121]. Of relevance to the existing discussion, in part, it defines a medical device as any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

I) diagnosis, prevention, monitoring, treatment or alleviation of disease;

II) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

III) investigation, replacement or modification of the anatomy or of a physiological process;

and that does not achieve its intended action in or on the human body by pharmacological, immunological or metabolic means.

Within dentistry, the use of medical devices is common, however it is the use of custom-made medical devices that is most relevant to the issue of generic manufacturing in dentistry. A custom-made medical device is a device:

A. made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device

B. is intended:

(1) to be used only in relation to a particular individual; or

(2) to be used by the health professional to meet special needs arising in the course of his or her practice.

Within dentistry, custom-made medical device examples include crowns, bridges, dentures and various other specialised instruments, however the terminology in the Act states that if an existing "ordinary" medical device is adapted, altered, fashioned, modified or 'customised' to fit a patient, then it is not to be classified as a custom-made medical device. An example of such would be a preformed permanent dental crown that may require minimal fashioning in situ during restorative work; such a restoration is not classified as a custom-made medical device. Therefore the discerning feature or difference between a custom-made and a "customised" medical device is the fact that a custom-made device has been made at the specific request of a health care professional.

The key stipulation of the Act however is that custom-made medical devices are not required to be listed on the Australian Register of Therapeutic Goods (ARTG), however dentists and manufacturers still have an obligation under the Act to report their use, importation and manufacture for their patients. In a general sense, dentists do not need to notify the TGA for each individual patient receiving

a custom-made medical device. However one initial notification to the TGA is all that is required when the same kind of medical device is used; with the "same" being defined as same manufacturer, classification, same dentist importing or same Global Medical Device Nomenclature number (GMDN number). If a scenario arose where the same custom-made medical device was used, however it had been made by another generics manufacture, then a new notification is required to the TGA under the legislation.

Of all these legislative criteria, how might they apply to the different requirements of proprietary and generic manufacturers on a singular basis? Given that each component produced by a proprietary manufacturer are not done so at the request of a health practitioner, they are not classed as custom-made medical devices. As a result they are required to be approved prior to sale and subsequent installation upon the ARTG, a laborious and costly exercise both time-wise and financially. However, given that generic manufacturers are able produce design and manufacture componentry without the added burden of having their product be on the ARTG, there is more inherent freedom in their capacity to evolve and produce customisable solutions for the restorative clinician. In particular, this freedom is able to have a direct influence upon the implant componentry marketplace. Of concern is the lack of enforceable governance in this area, which may present an opportunity for the generic part manufacturers to unfairly compete against proprietary manufacturers who would seem to have greater obligations under the direction of the TGA, with the need to register their comparable products on the ARTG. The impact that such requirements have upon the public are yet to be fully

understood, however it would seem the reporting obligations are skewed in favour of custom-made medical device manufacturers. Whether this is a benefit to the public or not is an issue that would require further investigation.

The Act states that both manufacturers and suppliers, either clinicians or the laboratory selling custom-made medical devices, have regulatory obligations:

- A requirement to meet the essential principles (EPs) and thus demonstrate the quality, safety and performance of the device
- A requirement to apply a conformity assessment procedure to generate evidence that the device complies with the aspects of the Essential Principles (EPs)
- A requirement to notify the Therapeutic Goods Administration (TGA)
- A requirement to comply with advertising requirements
- A requirement to report adverse events

However, despite the fact that custom-made devices are exempt from the ARTG, all other obligations still apply to both manufacturer and dentists. This has been a requirement since 2002 in Australia, whereby the respective parties have needed to notify the TGA certain details if medical devices were either imported into Australia or manufactured locally, including: name and business address and a description relating to the "kind of device" that was being used. More recently, in February 2016 the regulations were amended, allowing for a two-month grace

period from the time of import or manufacture before needing to report the event, with notification to the TGA.

While sometimes the sponsor and the manufacturer are the same entity, for example a dental laboratory that supplies their products directly to dental professionals; it is also true that dentists and other allied oral healthcare providers are able to import custom-made medical devices from overseas. However, should this transaction occur, the dentist/healthcare provider becomes the sponsor and acquires certain obligations. Specifically, with respect to custom-made medical devices the regulations state[121]:

> *(1) The manufacturers of a custom-made medical device that is manufactured in Australia must, within 2 months after the medical device is first manufactured in Australia, give the following information about the device to the Secretary:*
>
> *(a) the manufacturer's name and business address;*
>
> *(b) a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).*
>
> *(2) The sponsor* (the dentist) *of a custom-made medical device that is imported into Australia must, within 2 months after the medical device is first imported into Australia, give the following information about the device to the Secretary:*
>
> *(a) The sponsor's name and address;*
>
> *(b) The manufacturer's name and business address;*

(c) A description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).

The notification process is simple, with sponsors or manufacturers needing only to complete a web-based, online notification form, within two months of the device being manufactured, or first imported, into Australia.

Given the different legislative obligations imposed upon the two manufacturing parties involved in this study, both proprietary and generic, there is a concern regarding the lack of consistency. As discussed earlier, there are no studies within the literature that attest to rigorously comparing biological and mechanical outcomes for patients that utilise generic componentry. Similarly, with a lack of examples available on the public record, where manufacturers or dentists have not followed the notification requirements desired by the TGA, it brings into question the enforceability of these guidelines. With generic componentry being readily available in Australia and the wider dental community, it has already been established that the cost is often less than the equivalent proprietary parts. In terms of reasons for their use therefore, both price and accessibility might seem motivation enough. However a lack of enforceable standards that ensures there exists some consistency in the components being used, may provide some artificial relief and sanctuary for clinicians utilising generic parts. For a restorative clinician, if there already exists a proprietary restorative solution for a particular case, then at very least there exists a choice. However if a proprietary solution is

unavailable, if the cost is less and if there are no enforceable consistent standards that encourage either compliance or attention, then it is quite understandable why a clinician might conduct a generic restorative workflow for a case, while potentially still achieving a pleasing clinical outcome. There is anecdotal evidence of this occurring throughout the dental community of Australia and certainly a survey of the wider dental community that questions the extent of generic component use would add to the scientific debate.

Additionally, as the treating clinician, there are no active educational campaigns aimed at informing on the respective differences that parts of proprietary and generic origins have. Instead of being able to make an informed choice between the proprietary and generic, as a result of this educational deficit, clinicians of all experience levels are indirectly led to believe that all parts are geometrically equal and interchangeable; as per the findings of this study, this is considered a falsehood.

From an economic point of view, the heavy investment made by generic manufacturers in the computer-assisted design and manufacture of componentry is only as worthwhile as the least accurate step in the process. Certainly, the detailed production method shared in this study by the generic manufacturer attests to a desire for a precise and accurate product. Unfortunately however, through the selection of the implant replica as a starting point, a clinically acceptable result was not achieved. Rather, the marginal gaps observed could result in the transfer of excessive forces through abutment screws, fixture walls or crestal bone, As

well as providing a recess for micro-biota accumulation, these effects may ultimately contribute to mechanical or biological failure in a clinical setting.

A quantitative analysis was considered for proprietary group and generic group specimens utilising the scan data obtained from the SkyScan1076 scanner. Given the inherent differences between the two abutment designs, it was unreliable to standardise an exact position in all specimens that could be used for comparison across the two groups. Certainly it is possible to use the scan data to derive a measurement between two surfaces. One such way is using the JAVA based image processing software, ImageJ (National Institute of Health, USA). However, it remains to be seen what value can be achieved by comparing the distances between two surfaces that *aren't* touching when these two surfaces are contacted in contrasting ways using two different designs. There is no inherent standardization possible that could derive scientifically useful or appropriate data. It would almost be like comparing how much space existed in a bowl full of oranges compared to a bowl full of apples- one could certainly measure it, but would it be possible to say that one is superior to the other simply because a value can be assigned to it?

As the software and analysis tool are unable to delineate below the level of 9μm, any surface that approximates one another that is smaller than this magnitude appears to touch, having no gap whatsoever, as demonstrated in the results chapter of this paper. While this may or may not be the actual magnitude of distance between the respective surfaces, it has been demonstrated previously by

authors that there are distances between fixtures and abutments that are less than the sensitivity described in this study[1].

For this reason, it was decided that a quantitative analysis was not appropriate given the heterogeneous nature of the specimens involved and difficulty with standardizing the two groups in the context of the study format.

From an investigative point of view, microtomography was an excellent non-destructive empirical tool for analysing the qualitative aspects of the implant-abutment connections. This has been supported by other authors as a research tool for both qualitative and quantitative analysis [108,122]. In this paper, for reasons described earlier, a qualitative analysis was performed only. The studies by Hamilton[1], Gigandent[3] and coworkers, and others, where a wider spread of implant specimens were used, lend themselves more to a quantitative analysis. In that situation, comparison of fit can be compared between a variety of implant manufacturers and one abutment producer.

The difficulty encountered when using computed microtomography as the only investigative tool arises at the submicron level in terms of resolving spaces between the respective components when the derived images demonstrate apparent touching of opposing surfaces. In reality however, a different analytic method may find these components to be separated[1]. For this reason, there can be inherent limitations in using computed microtomography for rigorous quantitative differentiation and analysis, and may only be used confidently within the range of

specificity advised by the respective scanners themselves. Unfortunately, the author did not have access to a computed microtomography scanner capable of any greater magnification, however given the range that these scanners in general are effective over is between 5-50 μm[108], then in terms of accurately quantifying the marginal gap, we are yet to identify a non-destructive technique to accurately achieve this.

This qualitative analysis however revealed a number of unique features that would not have been previously evident. Significantly, there was a discernable difference in the final abutment screw thread position between the two groups; twice the number of contact points in generic group specimens than proprietary group specimens; the length and breadth of the anti-rotational hexagon is significant in terms of componentry fit, reduction of which permits a better fit for generic componentry. This was certainly evident following the additional adjustment of specimen 4 and re-scanning. While both abutment types were successful in achieving a connection with anti-rotation, the quantification of the initial laboratory replica made by Stoneglass Industries was certainly one aspect of the methodology that lead to error within the fitting of the generic parts. As described in Chapter 3.1.2 the staff at Stoneglass Industries performed a test run on an initial abutment through checking the fit by hand under light microscopy. A 'soft touch' technique was described by the staff, with any necessary changes made in 5 μm increments to the CAD file prior to a re-machining process. As has been well established in this study, the base measuring method was with the laboratory replica, however the resulting generic abutments were too wide for the fixtures at

the superior aspect of implant platform and they were certainly to long from an abutment hexagon viewpoint. Neither of these errors in production could be reliably assessed using light microscopy and a ‘soft touch’ alone; rather the presence of a Micro-CT system within the generic manufacture QA/QC program would have been a strong benefit to their processes; as would the ability to check the fit against an implant fixture itself, with a proprietary abutment screw.

Chapter 6 Conclusion

A comparison between proprietary and generic abutments as they pertain to implant fixtures has revealed that different designs and methodologies can be utilised for the purposes of attaching to a common implant fixture. While it may be possible to construct a generic replacement for a proprietary component, careful consideration needs to be given to how the generic was made. Issues with the construction of generic abutments were found in this study that led to abutment-fixture marginal opening and misfit. While it might present a less expensive restorative option, a generic component that has incorporated design inaccuracies may have subsequent flow-on clinical affects, comprising both the mechanical and biologic aspects of implant therapy.

There were some relative limitations in the study with respect to the resolution capability of the Micro-CT unit. The SkyScan 1076 unit was able to scan our metallic samples to a resolution of 9 μm, which lacks the detail available using other scanning methodologies such as electron microscopy. This range is a stark improvement on previous scanners that ranged up as high as 50 μm[108]. One of the major benefits of being able to analyse with any Micro-CT however is the non-destructive internal analysis of a sample, something that would not have been possible with an electron microscopy setup. This method would have required specimens to be embedded, sectioned and treated for debris removal before analysis[1] and opened up to potential artefact creation within the specimens.

Generic implant components and manufacturers are loosely regulated in Australia, requiring voluntary notification to the Therapeutic Goods Administration within two months of importation into the country or of manufacture. While these guidelines are in place, their understanding within the wider dental community is poorly understood. This study may be used as part of an evidence supported educational campaign that is aimed at both the public and the dental profession would assist in raising the standard of care for patients in Australia. Equally, standardisation insofar as quality assurance and quality control for generic manufacturers would aid in the decision-making process for restorative clinicians. Simultaneously, this would aid in providing a level of reassurance for the patient as to the origin of any medical device being used. A number of factors were mentioned in this study regarding the clinical decision to utilise generic componentry, including cost, geographic availability and proprietary catalogue deficiencies. Further research is needed in the form of questionnaires for restorative clinicians to further expand on the reasons discussed here. Identifying these reasons will assist in formulating and improving on policy and standardisation in the restoration of dental implants, and improve patient outcomes. At present there is also a lack of available evidence into the extent of clinical generic componentry use. This deficiency, combined with an understanding of how it performs in vivo from both a biological and mechanical perspective is a significant concern for the discipline and requires further research.

The decision to provide a laboratory replica to the generics manufacturer, Stoneglass Industries, was made in an attempt at replicating more realistic clinical conditions. Equally, this choice was made in response to an exchange between the author and the generics manufacturer, who requested a replica over an implant from the outset. In terms of clinically relevant data, this is as close to a real-world exchange as could be hoped for under the circumstance. This same exchange would occur between clinicians and generic component manufacturers the world over on occasion when a component is required that is outside the manufacturer's own library of parts. The errors identified in this study have served to enforce the point of requiring the most accurate precursor to reverse engineer from if generic components are to be used. Equally, the results serve as a warning, advising caution in the face of unregulated generic manufacture of componentry, particularly in light of there being no forthcoming description of fabrication methodologies easily available to restorative clinicians.

Within this study, the use of proprietary componentry appears to be a reliable and effective restorative option. The fit of proprietary componentry in this study was excellent and within the limitations of the scanning methodology, provided evidence that the unique design of the Neoss ProActive fixture and corresponding Ti NeoLink abutment were well suited in their close adaption of componentry. No marginal gaps were observed for proprietary specimens.

References

1. Hamilton A, Judge RB, Palamara JE, Evans C. Evaluation of the fit of CAD/CAM abutments. International Journal Prosthodontics, 2013 Jul;26(4):370–80.

2. Alves da Cunha T de M, Correia de Araújo RP, Barbosa da Rocha PV, Pazos Amoedo RM. Comparison of fit accuracy between Procera custom abutments and three implant systems. Clinical Implant Dentistry and Related Research. 2012 Oct;14(5):772–7.

3. Gigandet M, Bigolin G, Faoro F, Bürgin W, Brägger U. Implants with original and non-original abutment connections. Clinical Implant Dentistry and Related Research. 2014 Apr;16(2):303–11.

4. Gallucci GO, Doughtie CB, Hwang JW, Fiorellini JP, Weber H-P. Five-year results of fixed implant-supported rehabilitations with distal cantilevers for the edentulous mandible. Clinical Oral Implants Research. Blackwell Publishing Ltd; 2009 Mar;20(6):1–7.

5. Adell R, Lekholm U, Rockler B, Brånemark PI. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. International Journal of Oral Surgery. 1981 Dec;10(6):387–416.

6. Adell R, Eriksson B, Lekholm U, Brånemark PI, Jemt T. Long-term follow-up study of osseointegrated implants in the treatment of totally edentulous jaws. The International Journal of Oral & Maxillofacial Implants. 1990;5(4):347–59.

7. Albrektsson T, Sennerby L. State of the art in oral implants. Journal of Clinical Periodontology. 1991 Jul;18(6):474–81.

8. Brånemark PI, Adell R, Breine U, Hansson BO, Lindström J, Ohlsson Å. Intra-osseous anchorage of dental prostheses. I. Experimental studies. Scandinavian Journal of Plastic Reconstructive Surgery. 1969;3(2):81–100.

9. Brånemark PI. Osseointegration and its experimental background. The Journal of Prosthetic Dentistry. 1983 Sep;50(3):399–410.

10. Bassi F, Carr AB, Chang T-L, Estafanous EW, Garrett NR, Happonen R-P, et al. Psychologic outcomes in implant prosthodontics. The International Journal of Prosthodontics. 2013 Sep;26(5):429–34.

11. Fiske J, Davis DM, Frances C, Gelbier S. The emotional effects of tooth loss in edentulous people. British Dental Journal. 1998 Jan 24;184(2):90–3, discussion p79.

12. Beaumont J, McManus G, Darcey J. Differentiating success from survival

in modern implantology--key considerations for case selection, predicting complications and obtaining consent. British Dental Journal. 2016 Jan 15;220(1):31–8.

13. Dental implants. Benefit and risk. Boston; 1977. pp. 13–9.

14. Schnitman PA, Shulman LB. Recommendations of the consensus development conference on dental implants. Journal of the American Dental Association. 1979 Mar;98(3):373–7.

15. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. The International Journal of Oral & Maxillofacial Implants. 1986;1(1):11–25.

16. Smith DE, Zarb GA. Criteria for success of osseointegrated endosseous implants. The Journal of Prosthetic Dentistry. 1989 Nov;62(5):567–72.

17. Papaspyridakos P, Chen CJ, Singh M, Weber HP, Gallucci GO. Success criteria in implant dentistry: a systematic review. Journal of Dental Research. 2012 Mar;91(3):242–8.

18. Fürhauser R, Florescu D, Benesch T, Haas R, Mailath G, Watzek G. Evaluation of soft tissue around single-tooth implant crowns: the pink esthetic score. Clinical Oral Implants Research. 2005 Dec;16(6):639–44.

19. Meijer HJA, Stellingsma K, Meijndert L, Raghoebar GM. A new index for rating aesthetics of implant-supported single crowns and adjacent soft tissues--the Implant Crown Aesthetic Index. Clinical Oral Implants Research. 2005 Dec;16(6):645–9.

20. Annibali S, Bignozzi I, La Monaca G, Cristalli MP. Usefulness of the Aesthetic Result as a Success Criterion for Implant Therapy: A Review. Clinical Implant Dentistry and Related Research. Blackwell Publishing Ltd; 2009 Aug 6;14(1):3–40.

21. Jemt T. Regeneration of gingival papillae after single-implant treatment. International Journal of Periodontics & Restorative Dentistry. 1997 Aug;17(4):326–33.

22. Papaspyridakos P, Chen C-J, Chuang S-K, Weber H-P, Gallucci GO. A systematic review of biologic and technical complications with fixed implant rehabilitations for edentulous patients. The International Journal of Oral & Maxillofacial Implants. 2012 Jan;27(1):102–10.

23. Pjetursson BE, Brägger U, Lang NP, Zwahlen M. Comparison of survival and complication rates of tooth-supported fixed dental prostheses (FDPs) and implant-supported FDPs and single crowns (SCs). Clinical Oral Implants Research. 2007 Jun;18 Suppl 3:97–113.

24. Jemt T, Bergendal B, Arvidson K, Bergendal T, Karlsson LDSDU, Linden B, et al. Implant-supported welded titanium frameworks in the edentulous maxilla: a 5-year prospective multicenter study. The International Journal of Prosthodontics. 2002 Nov;15(6):544–8.

25. Brägger U, Aeschlimann S, Bürgin W, Hämmerle CH, Lang NP. Biological and technical complications and failures with fixed partial dentures (FPD) on implants and teeth after four to five years of function. Clinical Oral Implants Research. 2001 Feb;12(1):26–34.

26. Ortorp A, Jemt T. Clinical experiences of implant-supported prostheses with laser-welded titanium frameworks in the partially edentulous jaw: a 5-year follow-up study. Clinical Implant Dentistry and Related Research. 1999;1(2):84–91.

27. Wennerberg A, Jemt T. Complications in partially edentulous implant patients: a 5-year retrospective follow-up study of 133 patients supplied with unilateral maxillary prostheses. Clinical Implant Dentistry and Related Research. 1999;1(1):49–56.

28. Henry PJ, Laney WR, Jemt T, Harris D, Krogh PH, Polizzi G, et al. Osseointegrated implants for single-tooth replacement: a prospective 5-year multicenter study. The International Journal of Oral & Maxillofacial Implants. 1996 Jul;11(4):450–5.

29. Brägger U, Karoussis I, Persson R, Pjetursson B, Salvi G, Lang N. Technical and biological complications/failures with single crowns and fixed partial dentures on implants: a 10-year prospective cohort study. Clinical Oral Implants Research. 2005 Jun;16(3):326–34.

30. Salvi GE, Brägger U. Mechanical and technical risks in implant therapy. The International Journal of Oral & Maxillofacial Implants. 2009;24 Suppl:69–85.

31. Snauwaert K, Duyck J, van Steenberghe D, Quirynen M, Naert I. Time dependent failure rate and marginal bone loss of implant supported prostheses: a 15-year follow-up study. Clinical Oral Investigations. 2000 Mar;4(1):13–20.

32. Vehemente VA, Chuang S-K, Daher S, Muftu A, Dodson TB. Risk factors affecting dental implant survival. Journal of Oral Implantology. 2002;28(2):74–81.

33. De Bruyn H, Christiaens V, Doornewaard R, Jacobsson M, Cosyn J, Jacquet W, et al. Implant surface roughness and patient factors on long-term peri-implant bone loss. Periodontology 2000. 2017 Feb;73(1):218–27.

34. Becker ST, Beck-Broichsitter BE, Rossmann CM, Behrens E, Jochens A,

Wiltfang J. Long-term Survival of Straumann Dental Implants with TPS Surfaces: A Retrospective Study with a Follow-up of 12 to 23 Years. Clinical Implant Dentistry and Related Research. 2016 Jun;18(3):480–8.

35. Hasegawa T, Kawabata S, Takeda D, Iwata E, Saito I, Arimoto S, et al. Survival of Brånemark System Mk III implants and analysis of risk factors associated with implant failure. International Journal of Oral and Maxillofacial Surgery. Elsevier; 2016 Nov 14;0(0).

36. Buser D, Weber HP, Lang NP. Tissue integration of non-submerged implants. 1-year results of a prospective study with 100 ITI hollow-cylinder and hollow-screw implants. Clinical Oral Implants Research. 1990 Dec;1(1):33–40.

37. Snauwaert K, Duyck J, van Steenberghe D, Quirynen M, Naert I. Time dependent failure rate and marginal bone loss of implant supported prostheses: a 15-year follow-up study. Clinical Oral Investigations. 2000 Mar;4(1):13–20.

38. Sahin S, Cehreli MC. The significance of passive framework fit in implant prosthodontics: current status. Implant Dentistry. 2001;10(2):85–92.

39. Carlsson L. Built-in strain and untoward forces are the inevitable companions of prosthetic misfit. Nobelpharma News; 1994.

40. Sones AD. Complications with osseointegrated implants. The Journal of Prosthetic Dentistry. 1989 Nov;62(5):581–5.

41. Taylor TD, Agar JR, Vogiatzi T. Implant prosthodontics: current perspective and future directions. The International Journal of Oral & Maxillofacial Implants. 2000 Jan;15(1):66–75.

42. Taylor TD. Prosthodontic problems and limitations associated with osseointegration. The Journal of Prosthetic Dentistry. 1998 Jan;79(1):74–8.

43. Smedberg JI, Nilner K, Rangert B, Svensson SA, Glantz SA. On the influence of superstructure connection on implant preload: a methodological and clinical study. Clinical Oral Implants Research. 1996 Mar;7(1):55–63.

44. Larson TD. The clinical significance of marginal fit. Northwest Dentistry. 2012 Jan;91(1):22–9.

45. Alajaji NK, Bardwell D, Finkelman M, Ali A. Micro-CT Evaluation of Ceramic Inlays: Comparison of the Marginal and Internal Fit of Five and Three Axis CAM Systems with a Heat Press Technique. Journal of Esthetic Restorative Dentistry. 2016 Sep 29.

46. Clinical acceptability of crown margins versus marginal gaps as determined by pre-doctoral students and prosthodontists. Journal of Prosthodontics. 2005 ed. Blackwell Science Ltd; 2005 Dec;14(4):226–32.

47. McLean JW, Fraunhofer von JA. The estimation of cement film thickness by an in vivo technique. British Dental Journal. 1971 Aug 3;131(3):107–11.

48. Manso AP, Silva NRFA, Bonfante EA, Pegoraro TA, Dias RA, Carvalho RM. Cements and adhesives for all-ceramic restorations. Dental Clinics of North America. 2011 Apr;55(2):311–32–ix.

49. Carr AB, Brunski JB, Hurley E. Effects of fabrication, finishing, and polishing procedures on preload in prostheses using conventional "gold' and plastic cylinders. The International Journal of Oral & Maxillofacial Implants. 1996 Sep;11(5):589–98.

50. Ness EM, Nicholls JI, Rubenstein JE, Smith DE. Accuracy of the acrylic resin pattern for the implant-retained prosthesis. The International Journal of Prosthodontics. 1992 Nov;5(6):542–9.

51. Tan KB, Rubenstein JE, Nicholls JI, Yuodelis RA. Three-dimensional analysis of the casting accuracy of one-piece, osseointegrated implant-retained prostheses. The International Journal of Prosthodontics. 1993 Jul;6(4):346–63.

52. Kohavi D. Complications in the tissue integrated prostheses components: clinical and mechanical evaluation. Journal of Oral Rehabilitation. 1993 Jul;20(4):413–22.

53. Balshi TJ. An analysis and management of fractured implants: a clinical report. The International Journal of Oral & Maxillofacial Implants. 1996 Sep;11(5):660–6.

54. Kallus T, Bessing C. Loose gold screws frequently occur in full-arch fixed prostheses supported by osseointegrated implants after 5 years. The International Journal of Oral & Maxillofacial Implants. 1994 Mar;9(2):169–78.

55. Sahin S, Cehreli MC, Yalçin E. The influence of functional forces on the biomechanics of implant-supported prostheses--a review. Journal of Dentistry. 2002 Sep;30(7-8):271–82.

56. Isidor F. Influence of forces on peri-implant bone. Clinical Oral Implants Research. Blackwell Publishing Ltd; 2006 Oct;17 Suppl 2(S2):8–18.

57. Abduo J, Judge RB. Implications of implant framework misfit: a systematic review of biomechanical sequelae. The International Journal of Oral & Maxillofacial Implants. 2014 May;29(3):608–21.

58. Barbier L, Schepers E. Adaptive bone remodelling around oral implants under axial and nonaxial loading conditions in the dog mandible. The International Journal of Oral & Maxillofacial Implants. 1997 Mar;12(2):215–23.

59. Papavasiliou G, Kamposiora P, Bayne SC, Felton DA. Three-dimensional finite element analysis of stress-distribution around single tooth implants as a function of bony support, prosthesis type, and loading during function. The Journal of Prosthetic Dentistry. 1996 Dec;76(6):633–40.

60. Jemt T, Lie A. Accuracy of implant-supported prostheses in the edentulous jaw: analysis of precision of fit between cast gold-alloy frameworks and master casts by means of a three-dimensional photogrammetric technique. Clinical Oral Implants Research. 1995 Sep;6(3):172–80.

61. Clelland NL, Seidt JD, Daroz LGD, McGlumphy EA. Comparison of strains for splinted and nonsplinted implant prostheses using three-dimensional image correlation. The International Journal of Oral & Maxillofacial Implants. 2010 Sep;25(5):953–9.

62. Klineberg IJ, Murray GM. Design of superstructures for osseointegrated fixtures. Swedish Dental Journal Supplement. 1985;28:63–9.

63. Jemt T, Hjalmarsson L. In vitro measurements of precision of fit of implant-supported frameworks. A comparison between "virtual" and “physical” assessments of fit using two different techniques of measurements. Clinical Implant Dentistry and Related Research. 2012 May;14 Suppl 1:e175–82.

64. Carr AB, Gerard DA, Larsen PE. The response of bone in primates around unloaded dental implants supporting prostheses with different levels of fit. The Journal of Prosthetic Dentistry. 1996 Nov;76(5):500–9.

65. Millington ND, Leung T. Inaccurate fit of implant superstructures. Part 1: Stresses generated on the superstructure relative to the size of fit discrepancy. The International Journal of Prosthodontics. 1995 Nov;8(6):511–6.

66. Abduo J, Bennani V, Waddell N, Lyons K, Swain M. Assessing the fit of implant fixed prostheses: a critical review. The International Journal of Oral & Maxillofacial Implants. 2010 May;25(3):506–15.

67. Hayashi M, Watts DC, Ebisu S, Wilson NHF. Influence of vision on the evaluation of marginal discrepancies in restorations. Operative Dentistry. 2005 Sep;30(5):598–601.

68. Hayashi M, Wilson NHF, Ebisu S, Watts DC. Influence of explorer tip diameter in identifying restoration margin discrepancies. Journal of

Dentistry. Elsevier; 2005 Sep;33(8):669–74.

69. Kan JY, Rungcharassaeng K, Bohsali K, Goodacre CJ, Lang BR. Clinical methods for evaluating implant framework fit. The Journal of Prosthetic Dentistry. 1999 Jan;81(1):7–13.

70. Dedmon HW. Disparity in expert opinions on size of acceptable margin openings. Operative Dentistry. 1982;7(3):97–101.

71. Cox JF, Pharoah M. An alternative holder for radiographic evaluation of tissue-integrated prostheses. The Journal of Prosthetic Dentistry. 1986 Sep;56(3):338–41.

72. Cameron SM, Joyce A, Brousseau JS, Parker MH. Radiographic verification of implant abutment seating. The Journal of Prosthetic Dentistry. 1998 Mar;79(3):298–303.

73. Jemt F. Failures and complications in 391 consecutively inserted fixed prostheses supported by Branemark implants in edentulous jaws: a study of treatment from the time of prosthesis placement to the first annual checkup. The International Journal of Oral & Maxillofacial Implants. 1991;6(3):270–6.

74. Binon P, Sutter F, Beaty K. The role of screws in implant systems. The The International Journal of Oral & Maxillofacial Implants. 1994;Suppl 1(9):p 48-63.

75. Jemt T. In vivo measurements of precision of fit involving implant-supported prostheses in the edentulous jaw. The International Journal of Oral & Maxillofacial Implants. 1996 Mar;11(2):151–8.

76. Wee AG, Aquilino SA, Schneider RL. Strategies to achieve fit in implant prosthodontics: a review of the literature. The International Journal of Prosthodontics. 1999 Mar;12(2):167–78.

77. Michalakis KX, Hirayama H, Garefis PD. Cement-retained versus screw-retained implant restorations: a critical review. The International Journal of Oral & Maxillofacial Implants. 2003 Sep;18(5):719–28.

78. Ortorp A, Jemt T, Back T, Jalevik T. Comparisons of precision of fit between cast and CNC-milled titanium implant frameworks for the edentulous mandible. The International Journal of Prosthodontics. 2003 Mar;16(2):194–200.

79. Geng J-P, Tan KBC, Liu G-R. Application of finite element analysis in implant dentistry: A review of the literature. The Journal of Prosthetic Dentistry. 85(6):585–98.

80. Brosh T, Pilo R, Sudai D. The influence of abutment angulation on strains and stresses along the implant/bone interface: comparison between two

experimental techniques. The Journal of Prosthetic Dentistry. 1998 Mar;79(3):328–34.

81. Wise M. Fit of implant-supported fixed prostheses fabricated on master casts made from a dental stone and a dental plaster. The Journal of Prosthetic Dentistry. Elsevier; 2001 Nov;86(5):532–8.

82. Lie A, Jemt T. Photogrammetric measurements of implant positions. Description of a technique to determine the fit between implants and superstructures. Clinical Oral Implants Research. 1994 Mar;5(1):30–6.

83. Mulcahy C, Sherriff M, Walter JD, Fenlon MR. Measurement of misfit at the implant-prosthesis interface: an experimental method using a coordinate measuring machine. The International Journal of Oral & Maxillofacial Implants. 2000 Jan;15(1):111–8.

84. Wise GE, King GJ. Mechanisms of tooth eruption and orthodontic tooth movement. Journal of Dental Research. 2008 May;87(5):414–34.

85. Szmukler-Moncler S, Salama H, Reingewirtz Y, Dubruille JH. Timing of loading and effect of micromotion on bone-dental implant interface: review of experimental literature. Journal of Biomedical Materials Research. 1998;43(2):192–203.

86. Rieger MR, Mayberry M, Brose MO. Finite element analysis of six endosseous implants. The Journal of Prosthetic Dentistry. 1990;63(6):671–6.

87. Nakazato G, Tsuchiya H, Sato M, Yamauchi M. In vivo plaque formation on implant materials. The International Journal of Oral & Maxillofacial Implants. 1989;4(4):321–6.

88. Passos SP, Gressler May L, Faria R, Özcan M, Bottino MA. Implant-abutment gap versus microbial colonization: Clinical significance based on a literature review. Journal of Biomedical Materials Research Part B Applied Biomaterials. 2013 Oct;101(7):1321–8.

89. Belser UC, Grütter L, Vailati F, Bornstein MM, Weber H-P, Buser D. Outcome evaluation of early placed maxillary anterior single-tooth implants using objective esthetic criteria: a cross-sectional, retrospective study in 45 patients with a 2- to 4-year follow-up using pink and white esthetic scores. Journal of Periodontology. 2009 Jan;80(1):140–51.

90. A systematic review of the survival and complication rates of fixed partial dentures (FPDs) after an observation period of at least 5 years. Clinical Oral Implants Research. Munksgaard International Publishers; 2004;15(6):625–42.

91. Internal vs. external connections for abutments/reconstructions: a systematic review. Clinical Oral Implants Research. 2012 ed. 2012

Oct;23 Suppl 6(s6):202–16.

92. Lee J-H, Park J-M, Park E-J, Koak J-Y, Kim S-K, Heo SJ. Comparison of Customized Abutments Made from Titanium and a Machinable Precious Alloy. The International Journal of Oral & Maxillofacial Implants. 2016 Jan;31(1):92–100.

93. Binon PP. Evaluation of three slip fit hexagonal implants. Implant Dentistry. 1996;5(4):235–48.

94. Binon PP. The effect of implant/abutment hexagonal misfit on screw joint stability. The International Journal of Prosthodontics. 1996 Mar;9(2):149–60.

95. Binon PP. Evaluation of machining accuracy and consistency of selected implants, standard abutments, and laboratory analogs. The International Journal of Prosthodontics. 1995 Mar;8(2):162–78.

96. Lee J-H, Kim D-G, Park C-J, Cho L-R. Axial displacements in external and internal implant-abutment connection. Clinical Oral Implants Research. 2014 Feb;25(2):e83–9.

97. Martin WC, Woody RD, Miller BH, Miller AW. Implant abutment screw rotations and preloads for four different screw materials and surfaces. The Journal of Prosthetic Dentistry. Elsevier; 2001 Jul;86(1):24–32.

98. Dittmer S, Dittmer MP, Kohorst P, Jendras M, Borchers L, Stiesch M. Effect of Implant-Abutment Connection Design on Load Bearing Capacity and Failure Mode of Implants. The Journal of Prosthodontics. Blackwell Publishing Inc; 2011 Sep 12;20(7):510–6.

99. Weinberg L. The biomechanics of force distribution in implant-supported prostheses. The International Journal of Oral & Maxillofacial Implants. 1993;8(1):19–31.

100. Jemt T, Laney WR, Harris D, Henry PJ, Krogh PH, Polizzi G, et al. Osseointegrated implants for single tooth replacement: a 1-year report from a multicenter prospective study. The International Journal of Oral & Maxillofacial Implants. 1991;6(1):29–36.

101. Becker W, Becker BE. Replacement of maxillary and mandibular molars with single endosseous implant restorations: a retrospective study. The Journal of Prosthetic Dentistry. 1995 Jul;74(1):51–5.

102. Norton MR. An in vitro evaluation of the strength of an internal conical interface compared to a butt joint interface in implant design. Clinical Oral Implants Research. Munksgaard International Publishers; 1997 Aug 1;8(4):290–8.

103. Mollersten L, Lockowandt P, Linden LA. Comparison of strength and

failure mode of seven implant systems: an in vitro test. The Journal of Prosthetic Dentistry. 1997 Dec;78(6):582–91.

104. Norton MR. An in vitro evaluation of the strength of a 1-piece and 2-piece conical abutment joint in implant design. Clinical Oral Implants Research. 2000 Oct;11(5):458–64.

105. Sutter F, Weber HP, Sorensen J. The new restorative concept of the ITI dental implant system: design and engineering. International Journal of Periodontics & Restorative Dentistry 1993;13(5):409–31.

106. Hounsfield GN. Computerized transverse axial scanning (tomography). 1. Description of system. British Journal of Radiology. 1973 Dec;46(552):1016–22.

107. Elliott JC, Dover SD. X-ray microtomography. Journal of Microscopy. 1982 May;126(Pt 2):211–3.

108. Swain MV, Xue J. State of the art of Micro-CT applications in dental research. International Journal of Oral Science. 2009 Dec;1(4):177–88.

109. Littleton JT, Littleton ML. Conventional tomography. In: Gagliardi RA, Knight N, editors. A History of the radiological sciences. Radiology Centential, Inc; 1996. pp. 369–401.

110. Sennerby L, Wennerberg A, Pasop F. A new microtomographic technique for non-invasive evaluation of the bone structure around implants. Clinical Oral Implants Research. 2001 Feb;12(1):91–4.

111. Shahmoradi M, Lashgari M, Rabbani H, Qin J, Swain M. A comparative study of new and current methods for dental micro-CT image denoising. Dentomaxillofacial Radiology. 2016;45(3):20150302.

112. Park Y-S, Yi K-Y, Lee I-S, Jung Y-C. Correlation between microtomography and histomorphometry for assessment of implant osseointegration. Clinical Oral Implants Research. 2005 Apr;16(2):156–60.

113. Neoss Limited. Neoss Implant System Guidelines. United Kingdom: Neoss Limited; 2014 Sep pp. 1–192.

114. Neoss Limited. NeoLoc Implant Abutment Connection. 2013. pp. 1–2.

115. Neoss Limited. Crystaloc Abutment Screw. 2010. pp. 1–1.

116. Atieh MA, Ibrahim HM, Atieh AH. Platform switching for marginal bone preservation around dental implants: a systematic review and meta-analysis. Journal of Periodontology. 2010 Oct;81(10):1350–66.

117. Sesma N, Garaicoa-Pazmino C, Zanardi PR, Chun EP, Laganá DC.

Assessment of Marginal Bone Loss around Platform-Matched and Platform-Switched Implants - A Prospective Study. Brazilian Dental Journal. 2016 Nov;27(6):712–6.

118. Wagenberg B, Froum SJ. Prospective study of 94 platform-switched implants observed from 1992 to 2006. International Journal of Periodontics & Restorative Dentistry. 2010 Feb;30(1):9–17.

119. Abduo J, Lyons K, Bennani V, Waddell N, Swain M. Fit of screw-retained fixed implant frameworks fabricated by different methods: a systematic review. The International Journal of Prosthodontics. 2011 May;24(3):207–20.

120. Wanchek T, Nicholson S, Vujicic M, Menezes A, Ziebert A. Educational debt and intended employment choice among dental school seniors. The Journal of the American Dental Association. Elsevier; 2014 May;145(5):428–34.

121. Commonwealth of Australia. Therapeutic Goods (Medical Devices) Regulations 2002. 2002 pp. 1–149.

122. Prasad R, Al-Kheraif AA. Three-dimensional accuracy of CAD/CAM titanium and ceramic superstructures for implant abutments using spiral scan microtomography. The International Journal of Prosthodontics. 2013 Sep;26(5):451–7.

Appendix A:

Proprietary group ~ Neoss titanium NeoLink Mono abutments

Specimen 1

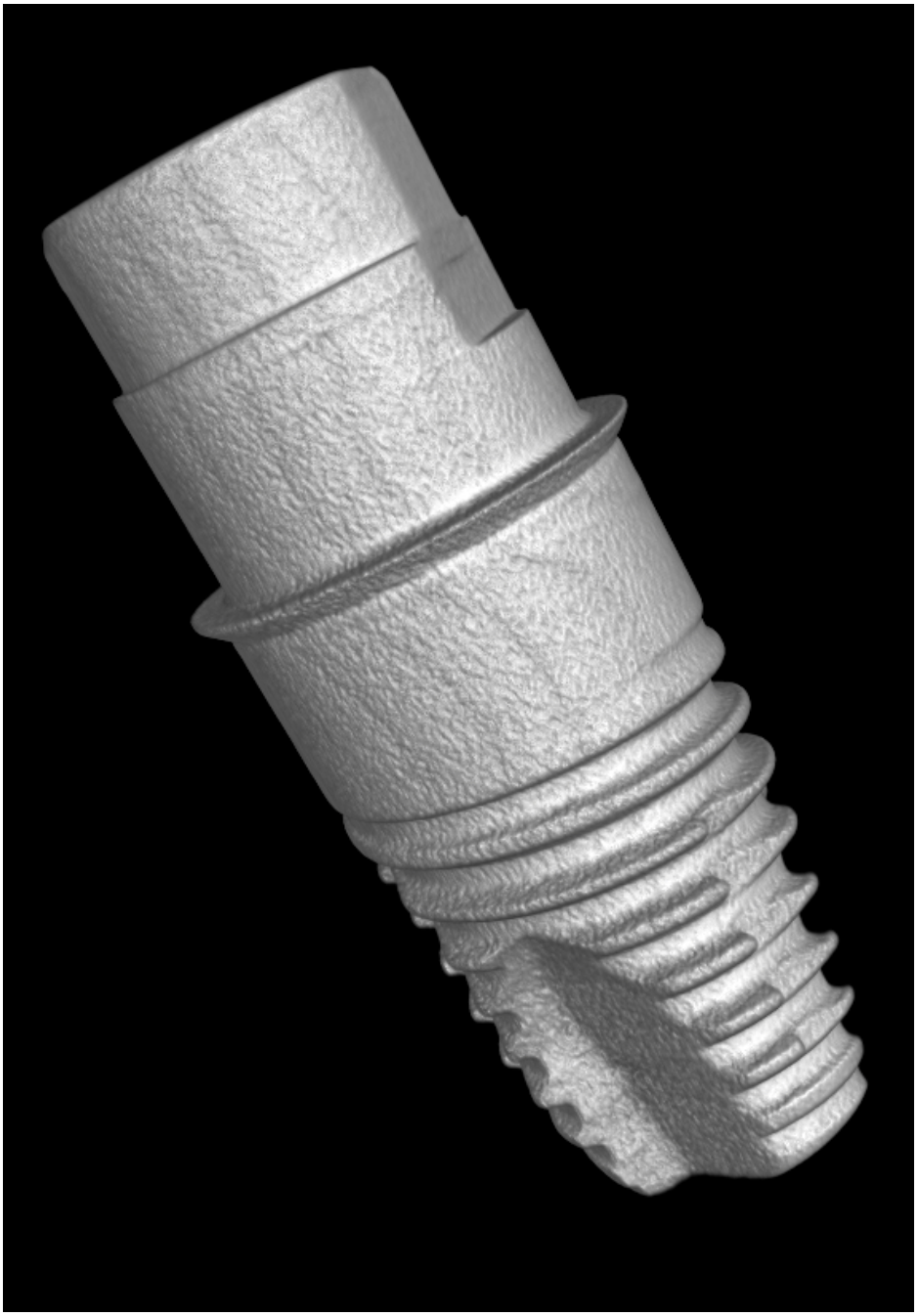


Figure 36: Specimen 1: External View 1 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

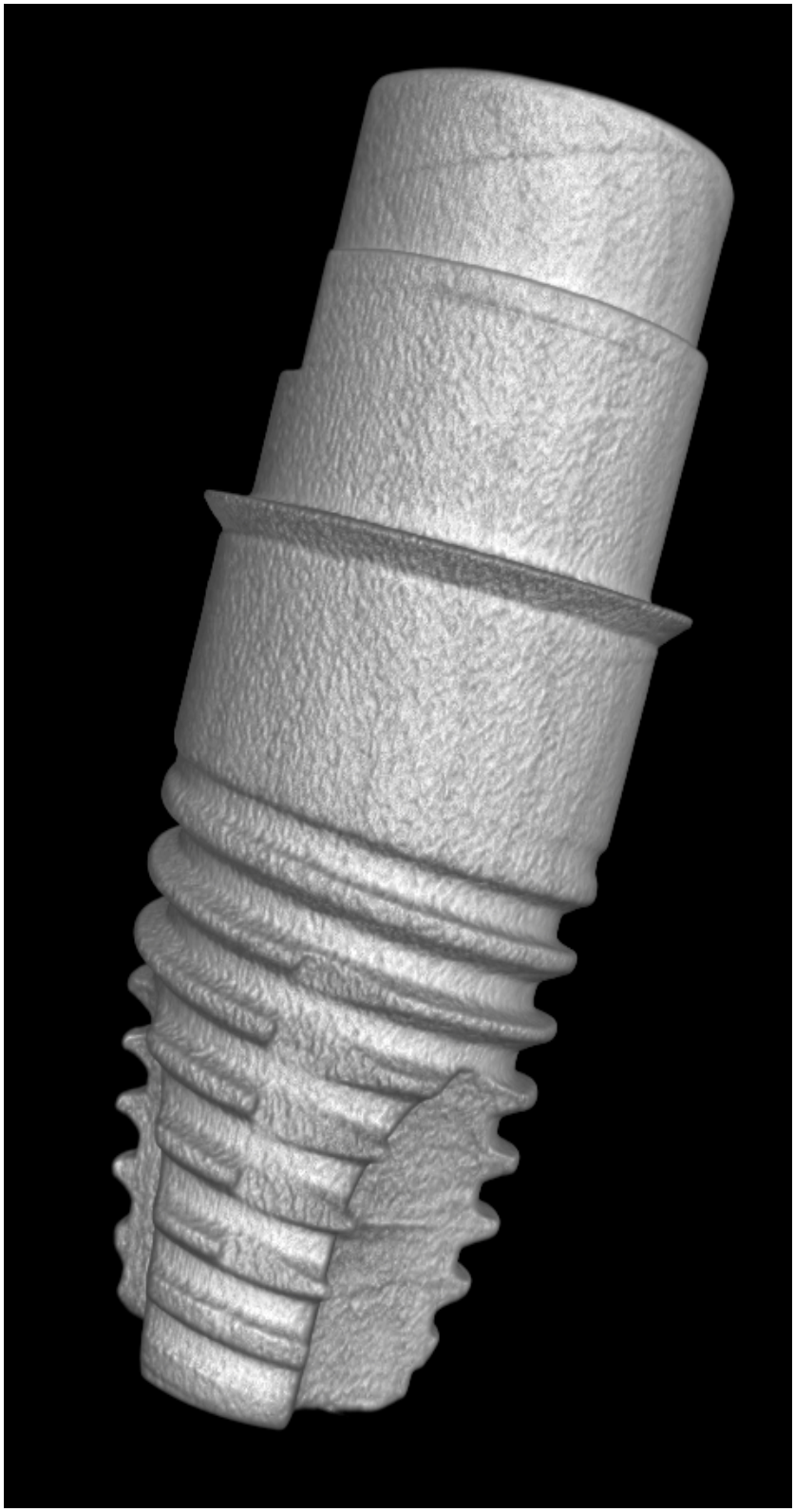


Figure 37: *Specimen 1: External View 2 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

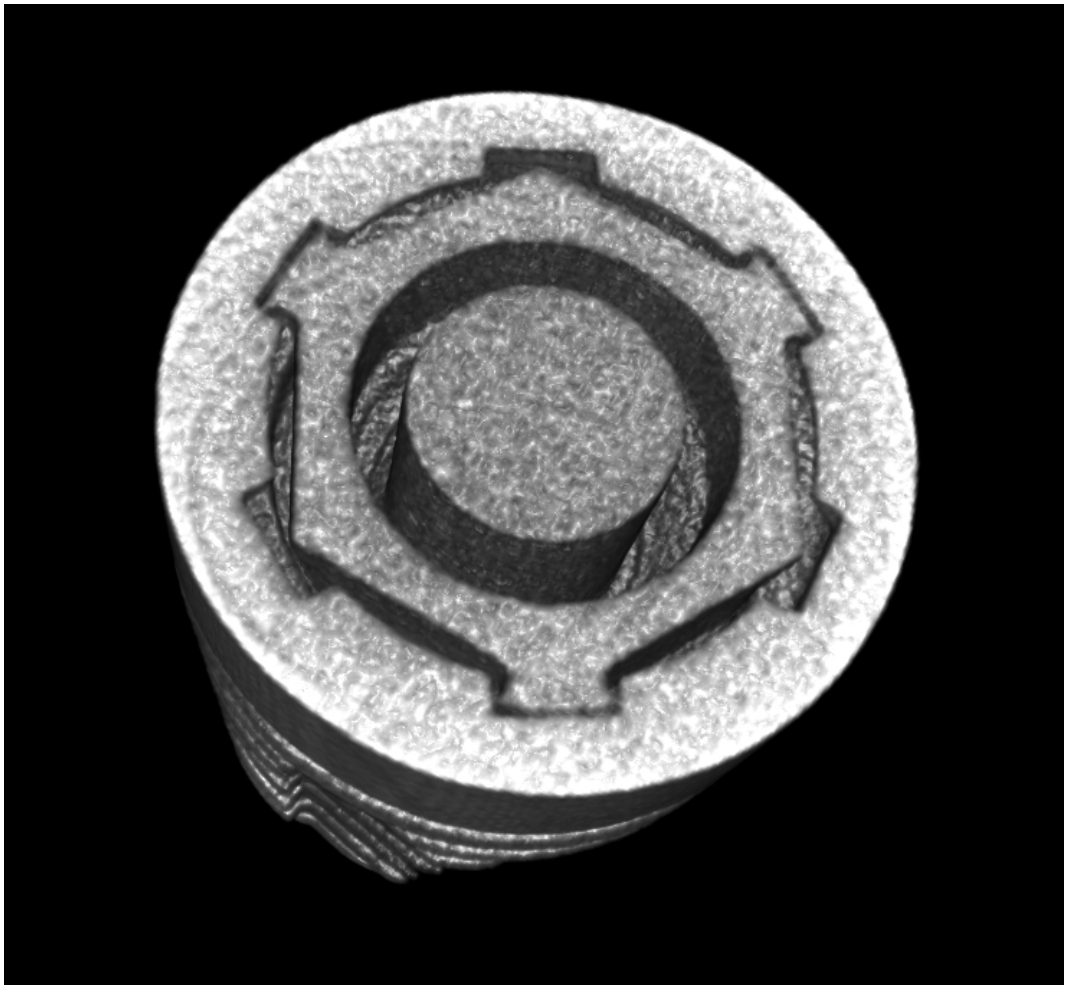


Figure 38: *Specimen 1: Cross Sectional View 1 (low) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

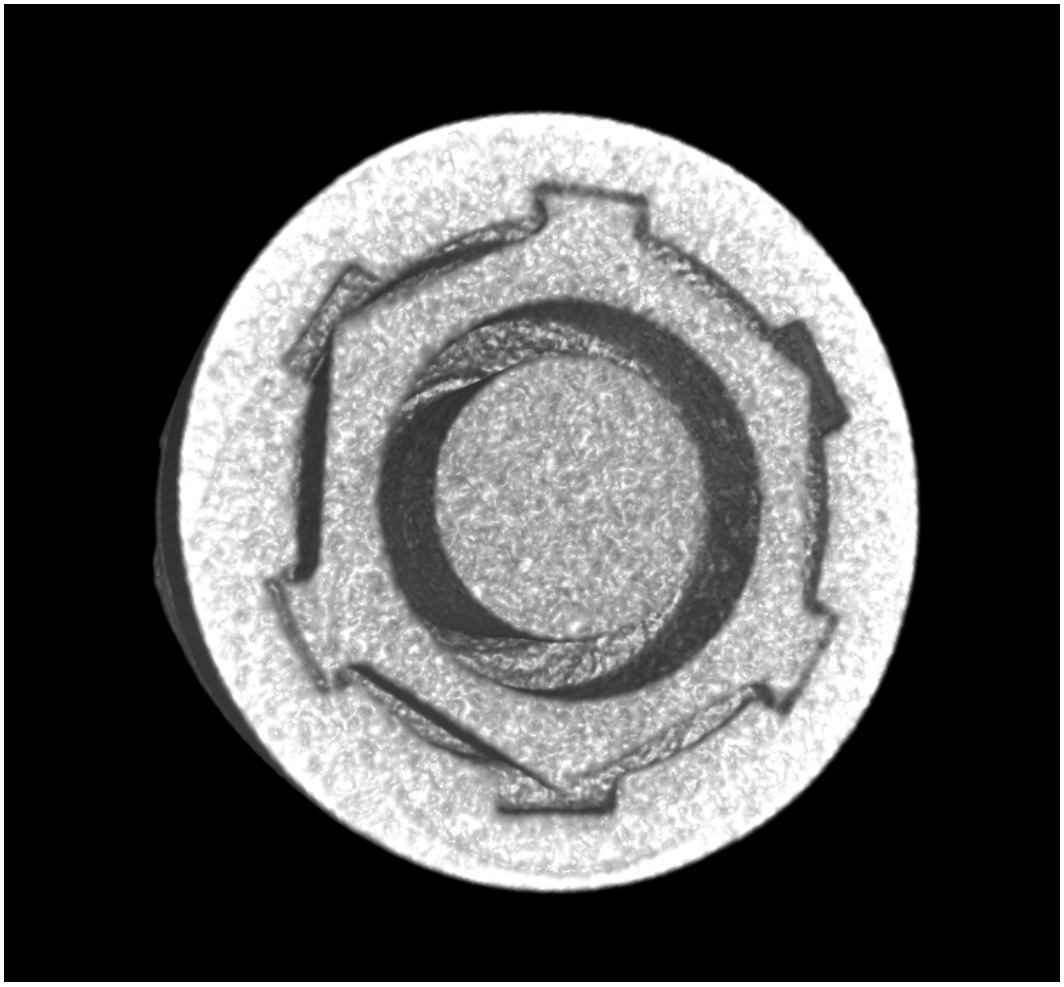


Figure 39: *Specimen 1: Cross Sectional View 1 (mid, with rotation of 30°) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

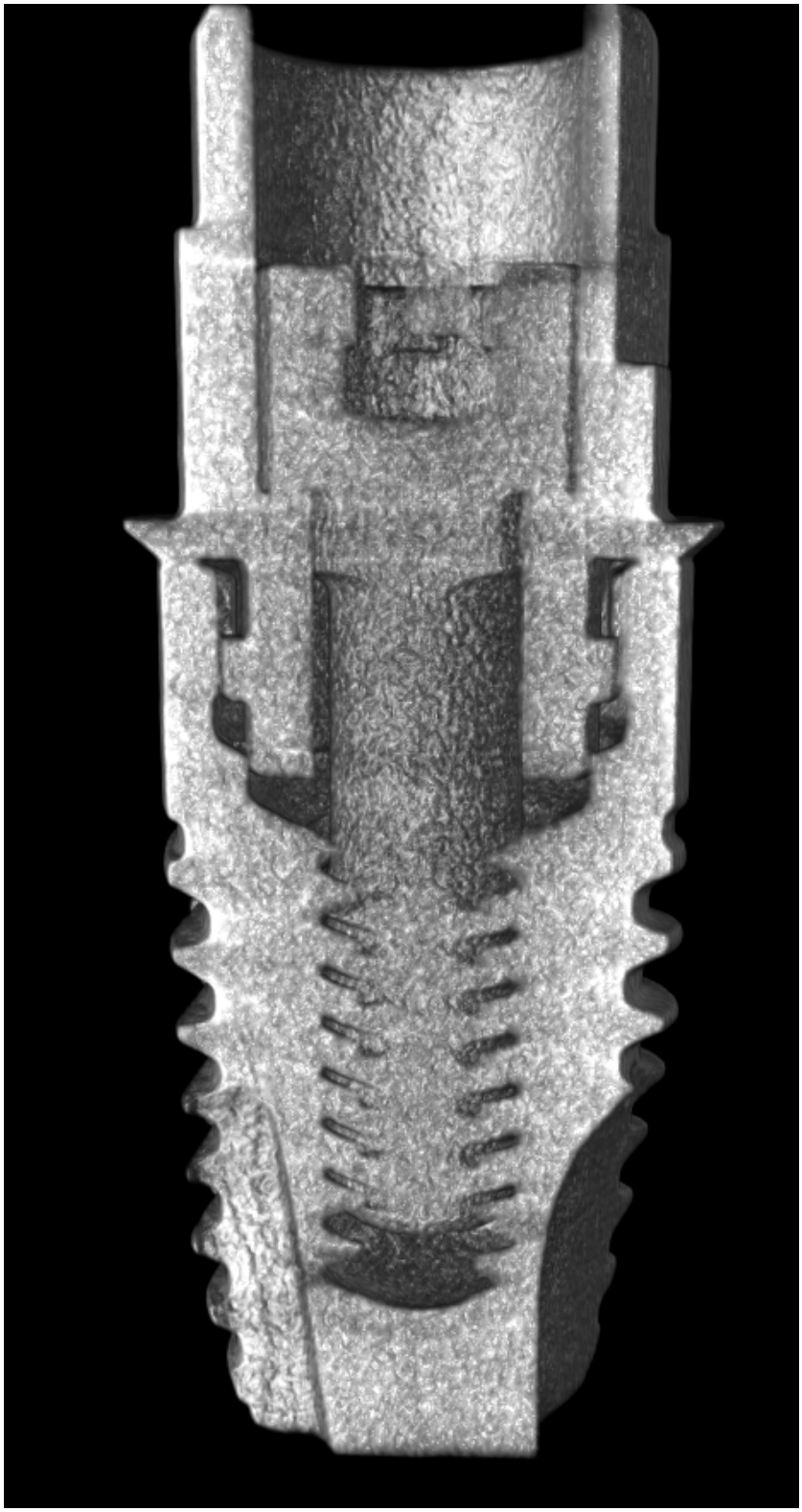


Figure 40: *Specimen 1: Coronal View 1 (midpoint) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

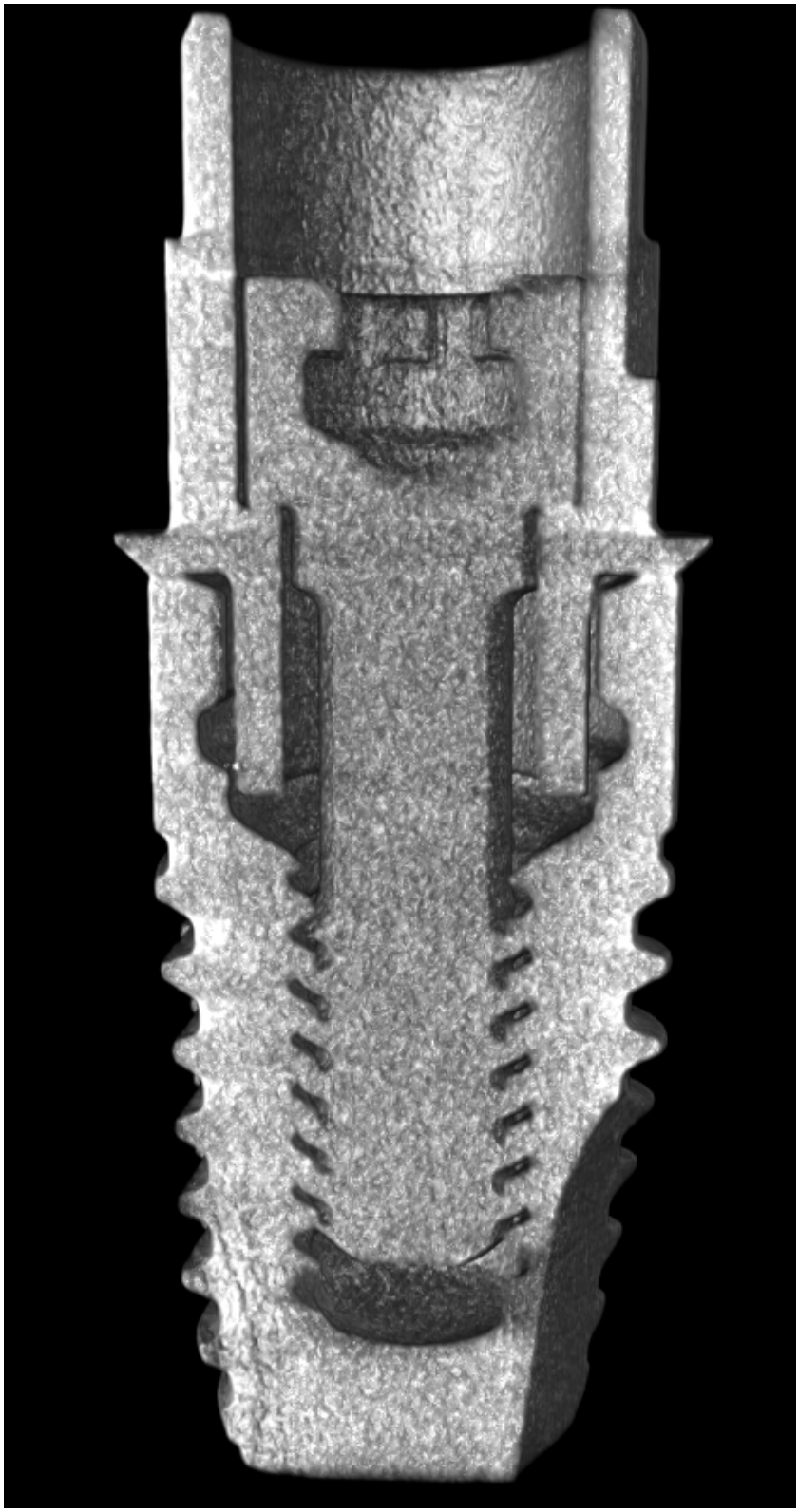


Figure 41: *Specimen 1: Coronal View 1 (anterior) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

Specimen 2

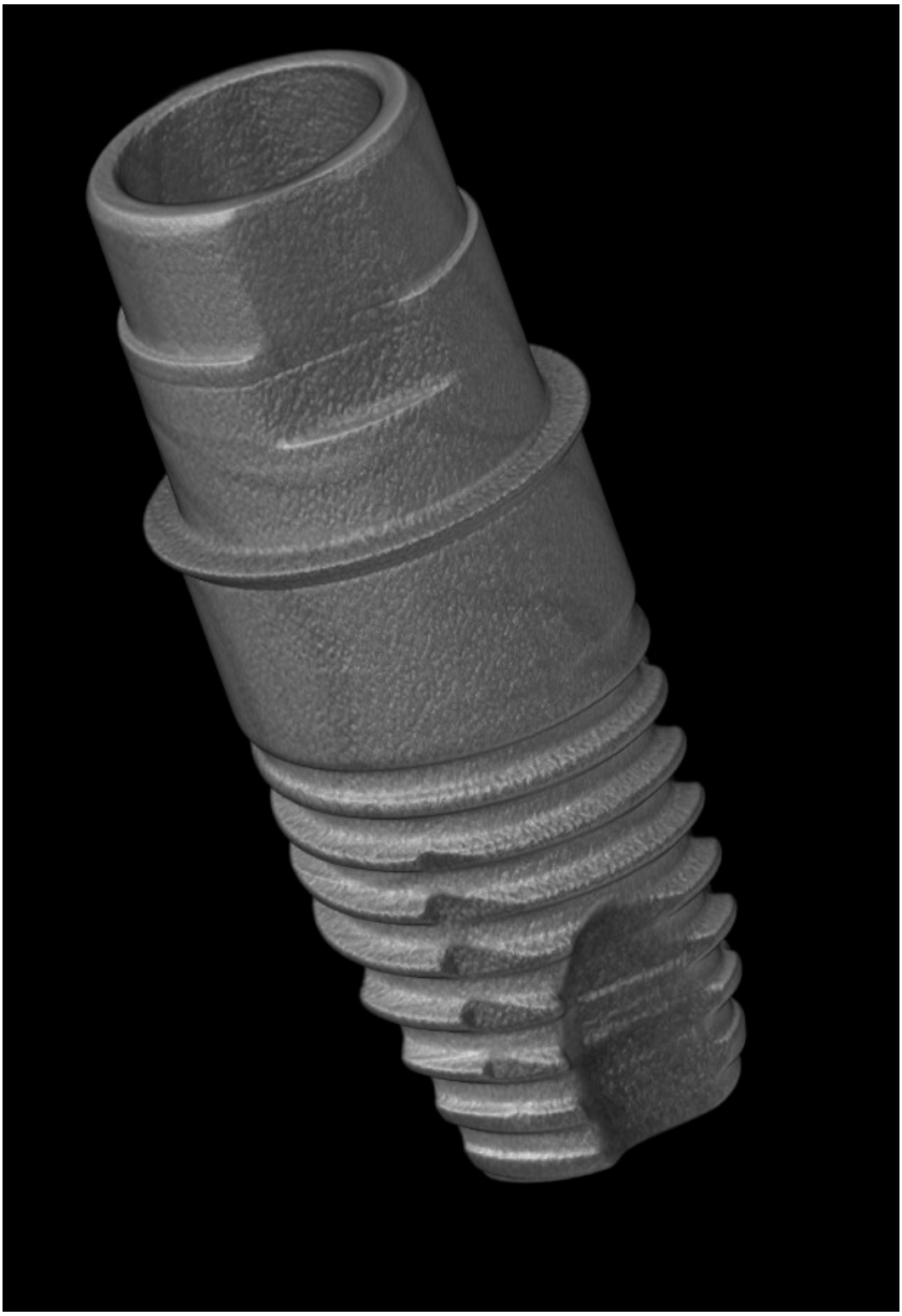


Figure 42: *Specimen 2: External View 1 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

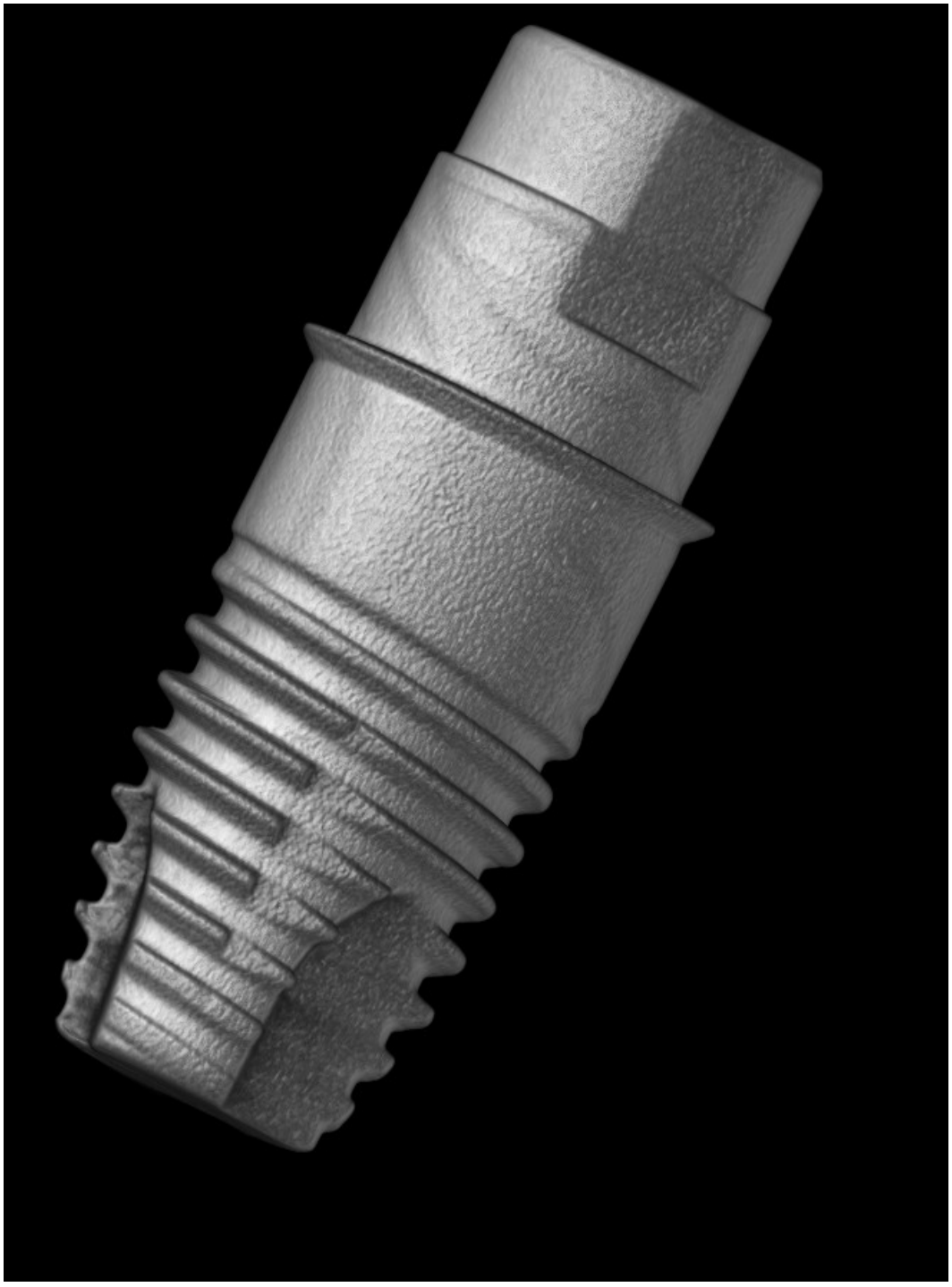


Figure 43: *Specimen 2: External View 2 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

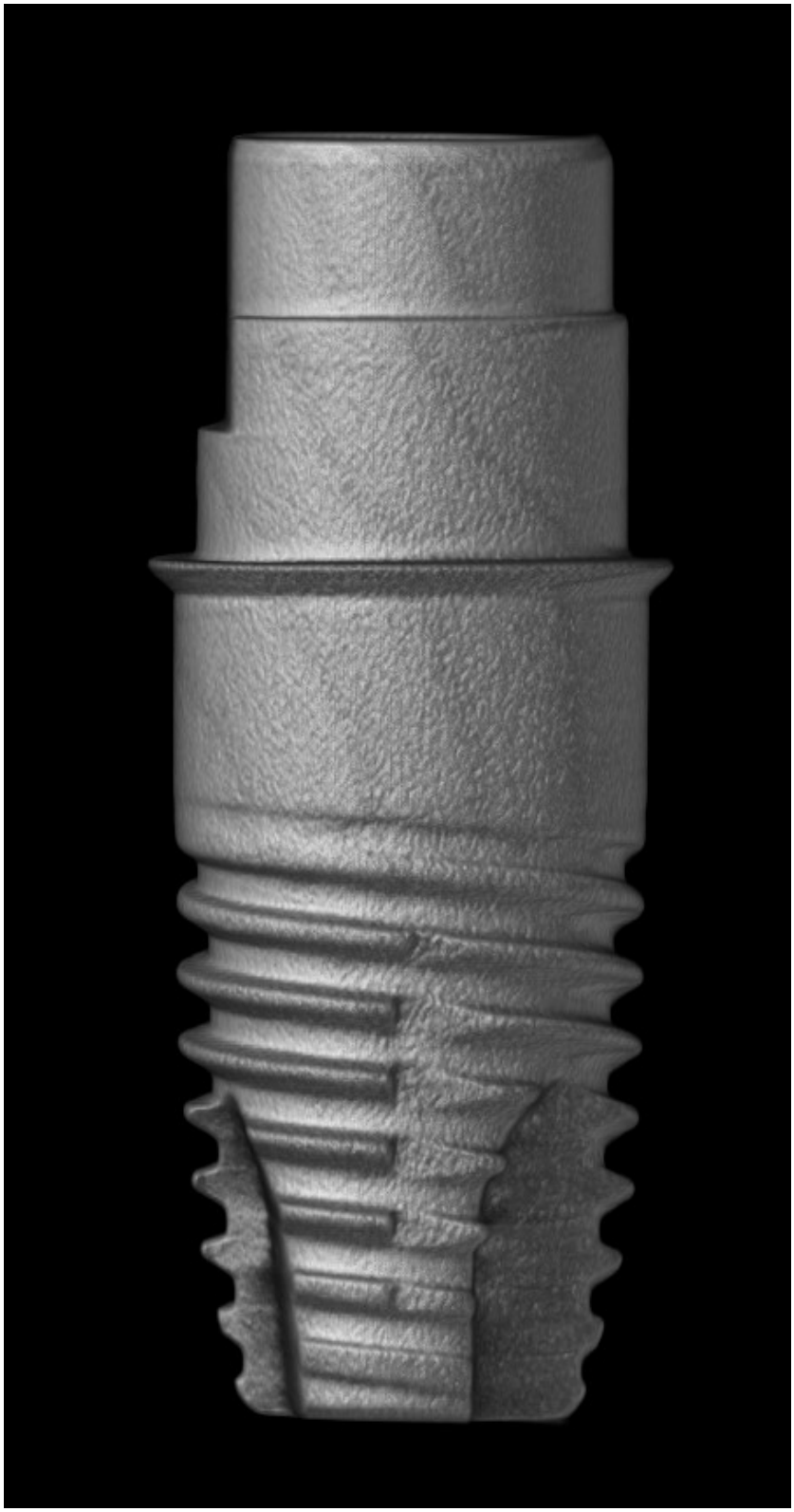


Figure 44: *Specimen 2: External View 3 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

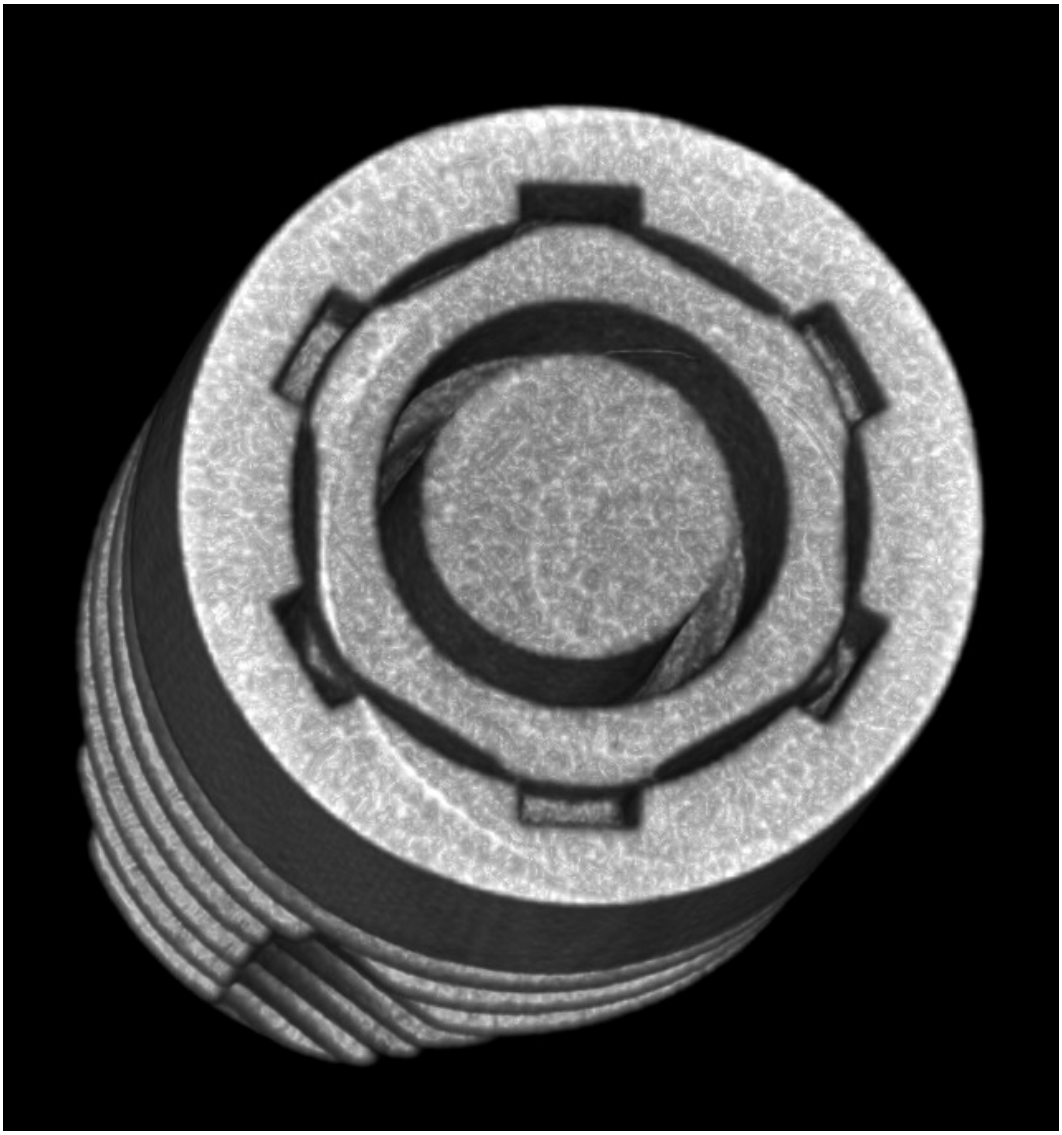


Figure 45: Specimen 2: Cross sectional View 1 (high) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

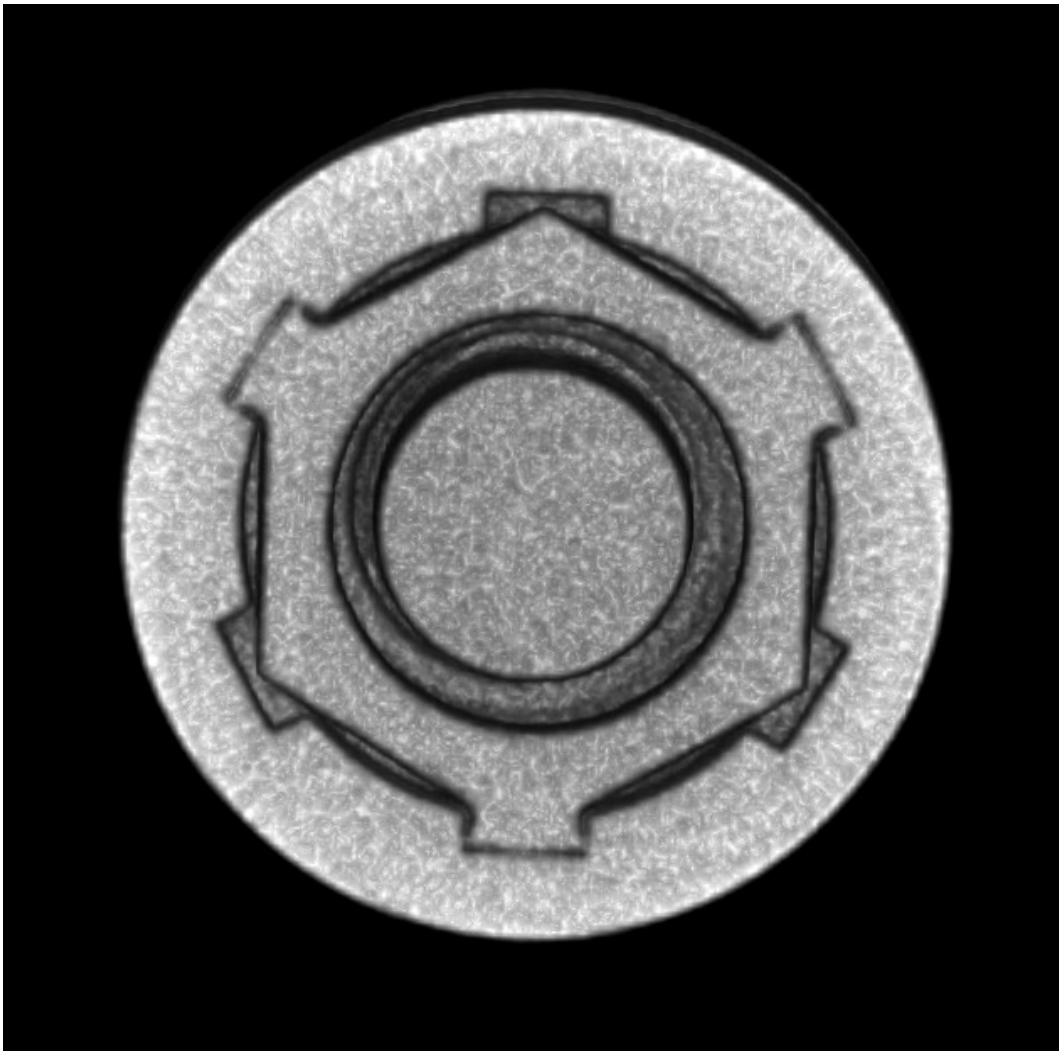


Figure 46: Specimen 2: Cross sectional View 2 (mid) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

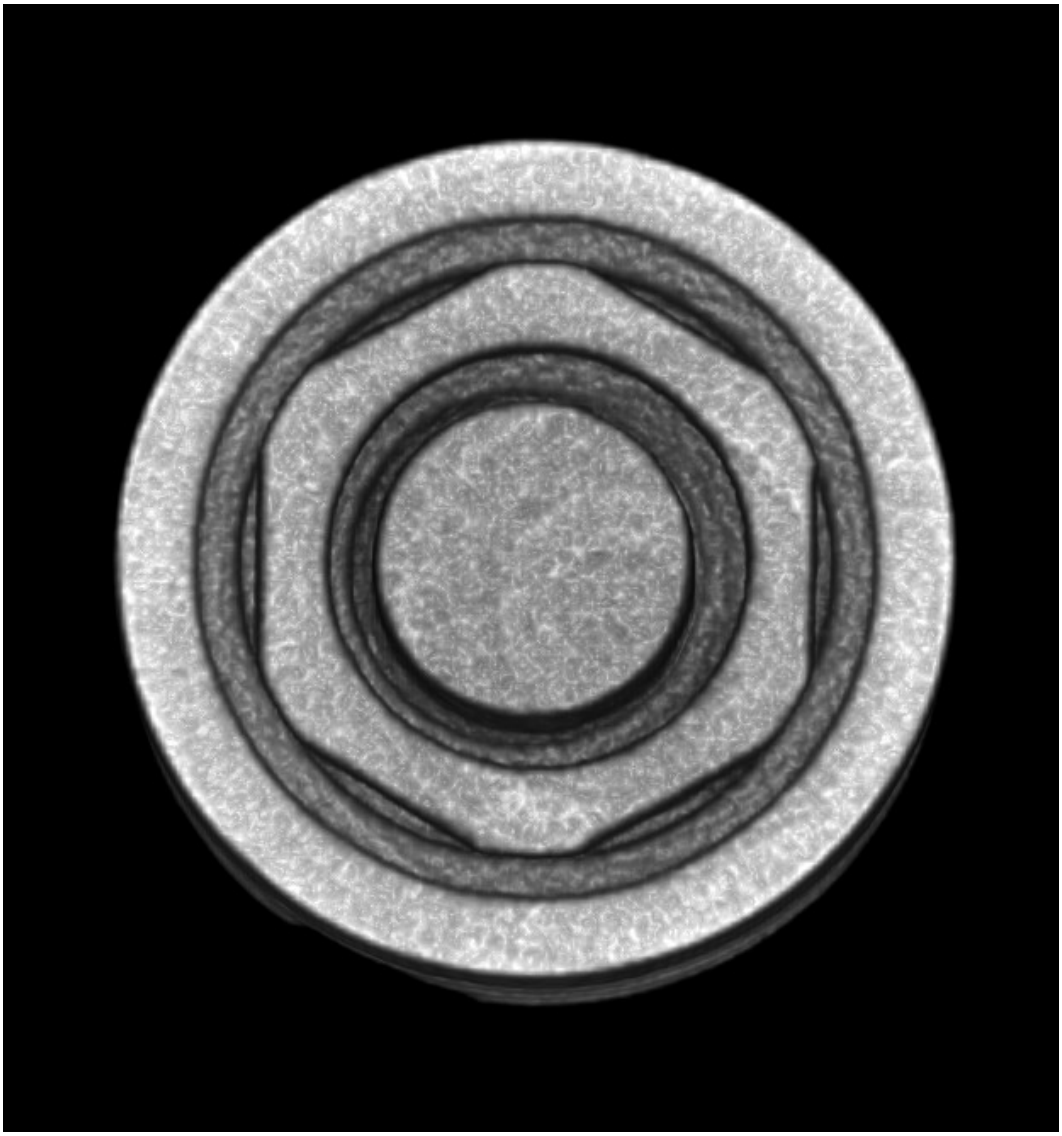


Figure 47: Specimen 2: Cross sectional View 2 (low) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

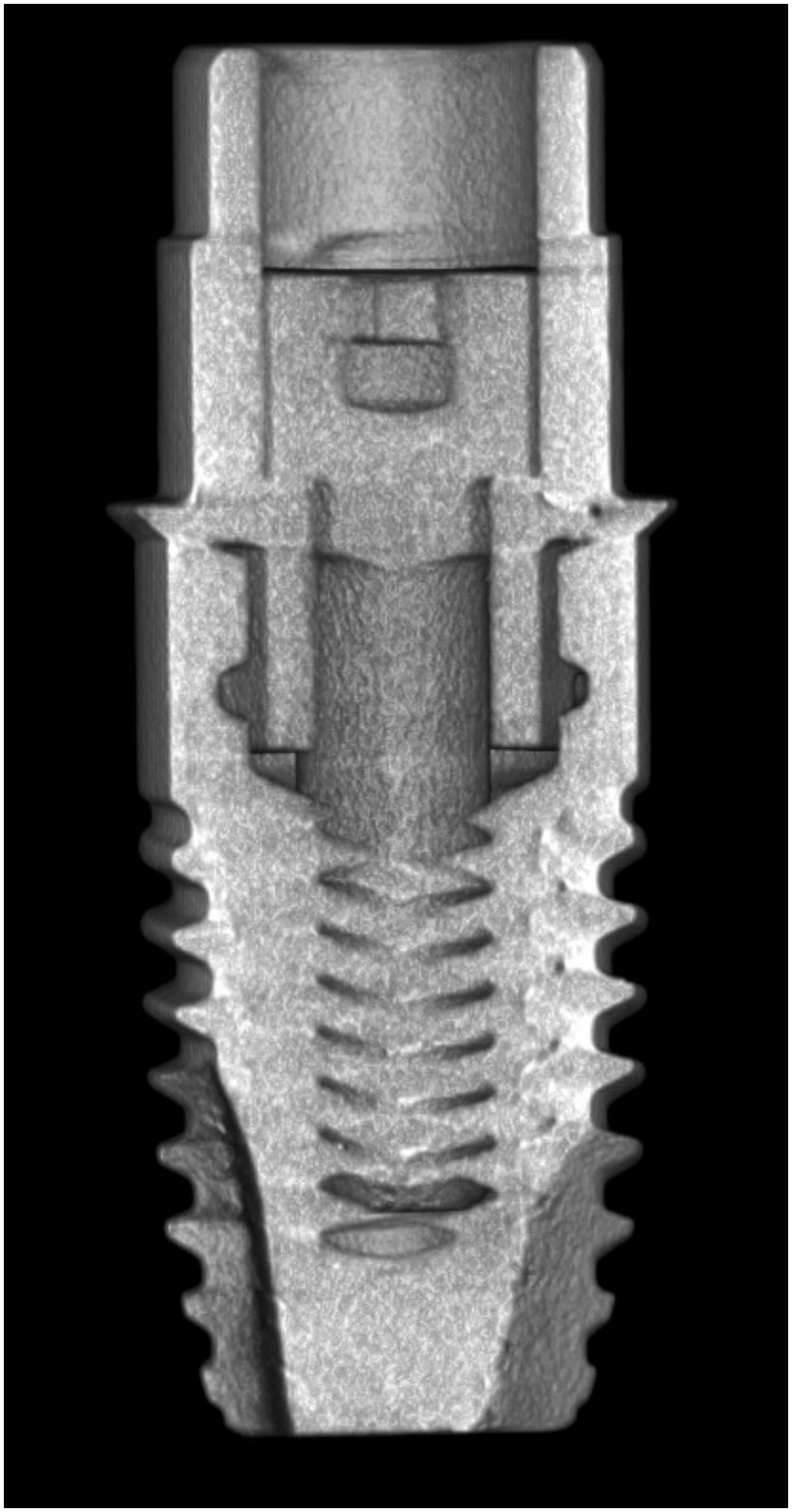


Figure 48: *Specimen 2: Coronal View 1 (anterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

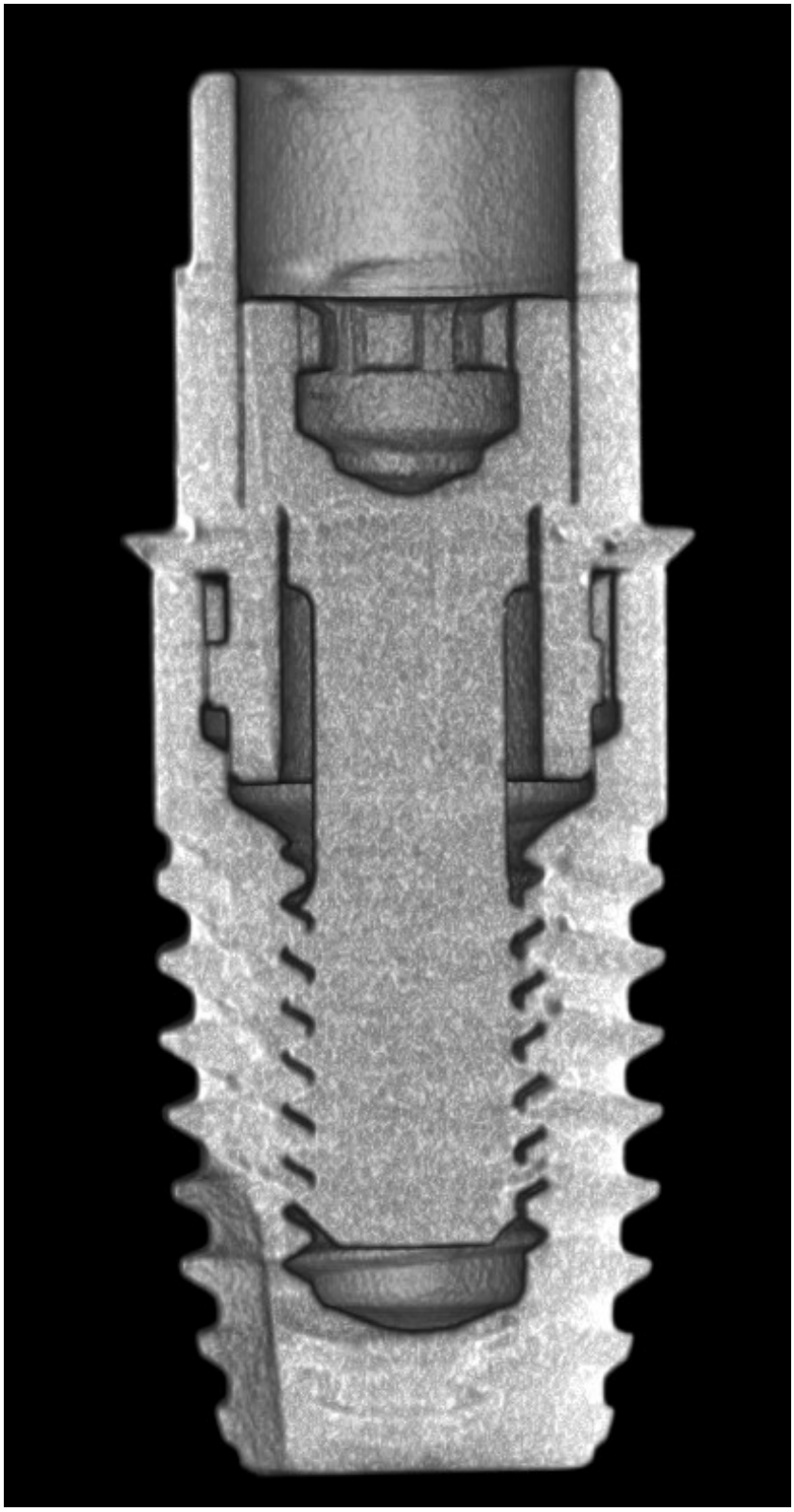


Figure 49: *Specimen 2: Coronal View 2 (midpoint) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

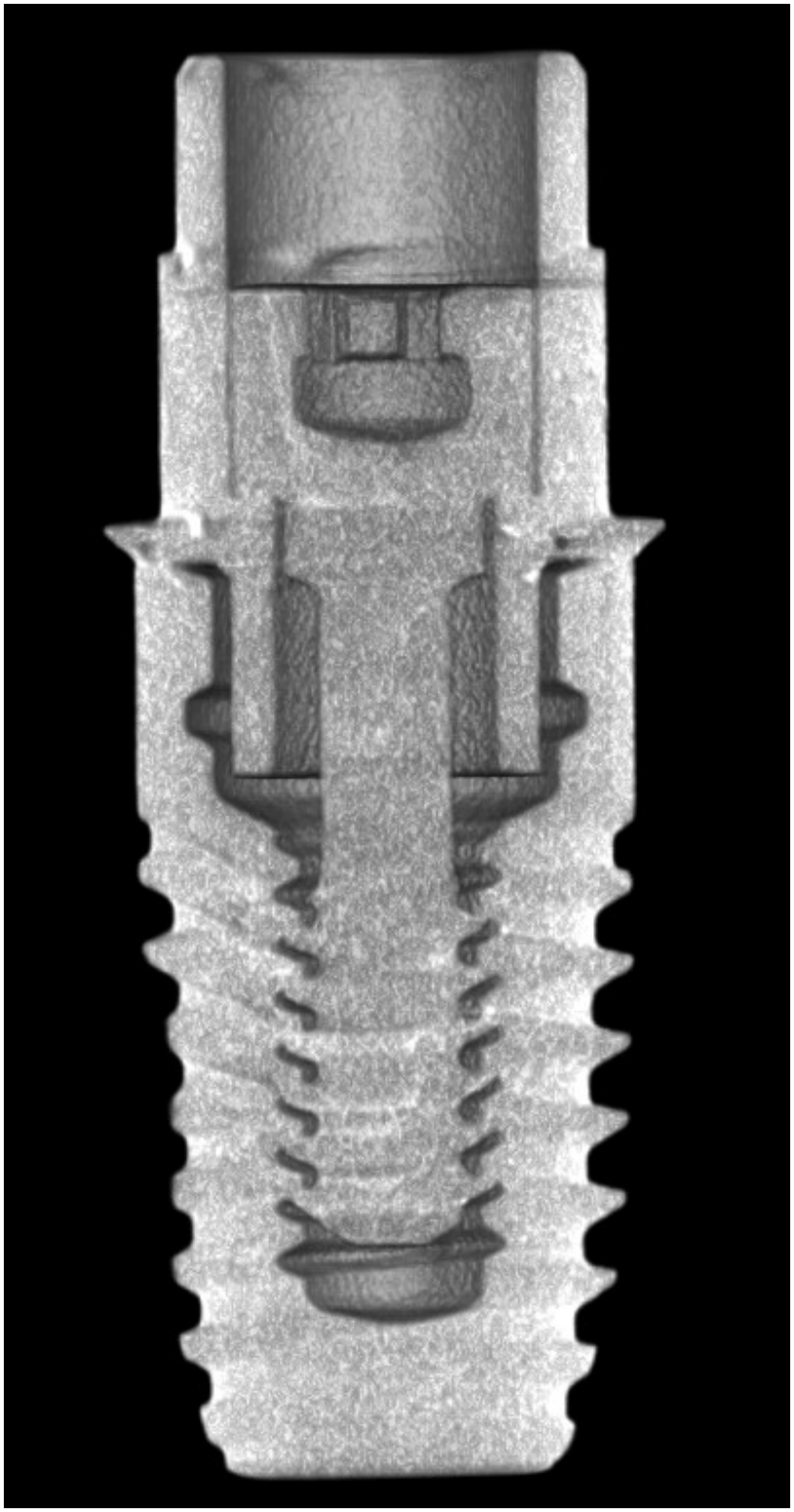


Figure 50: *Specimen 2: Coronal View 3 (posterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

Specimen 3

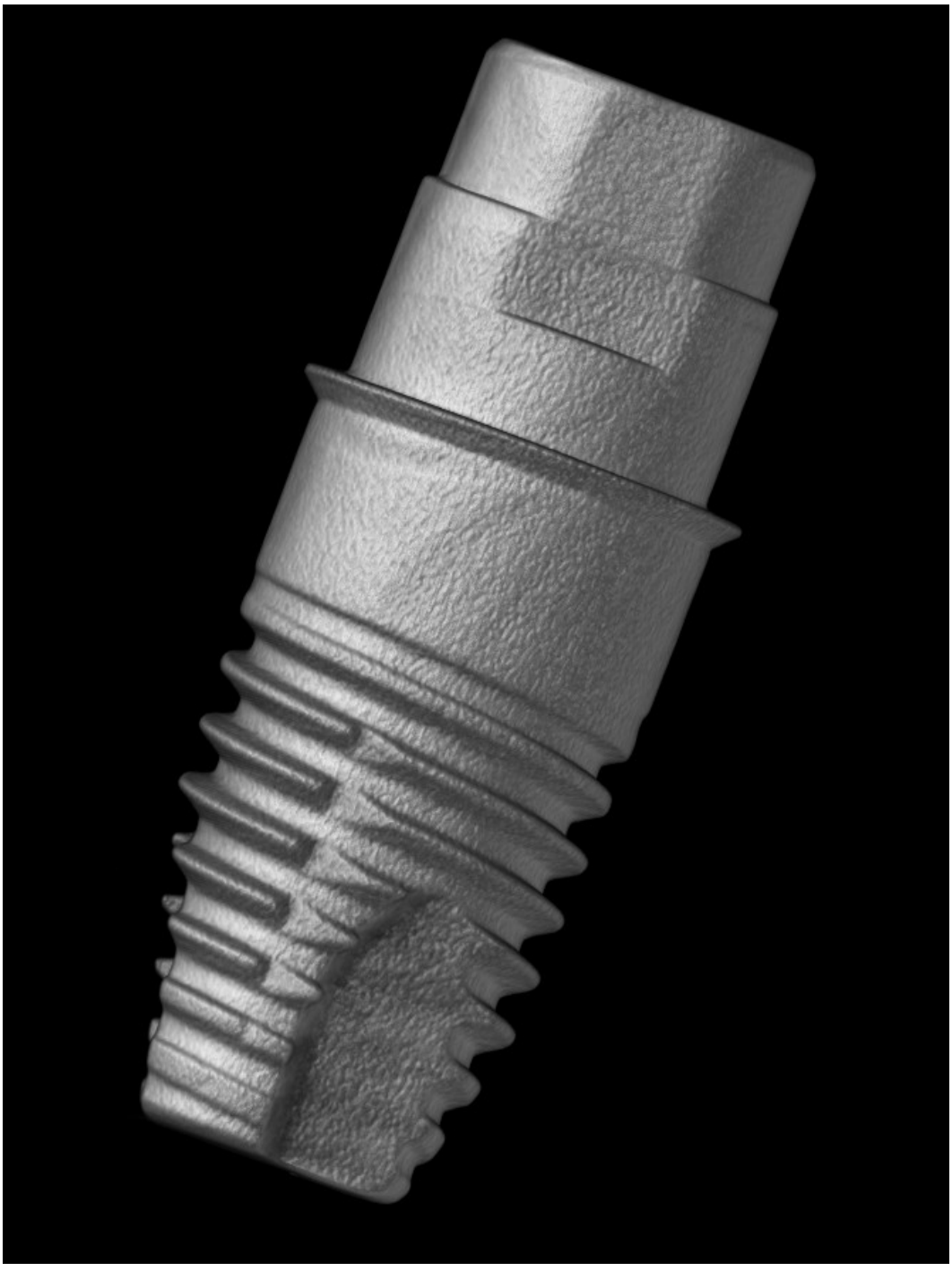


Figure 51: *Specimen 3: External View 1 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

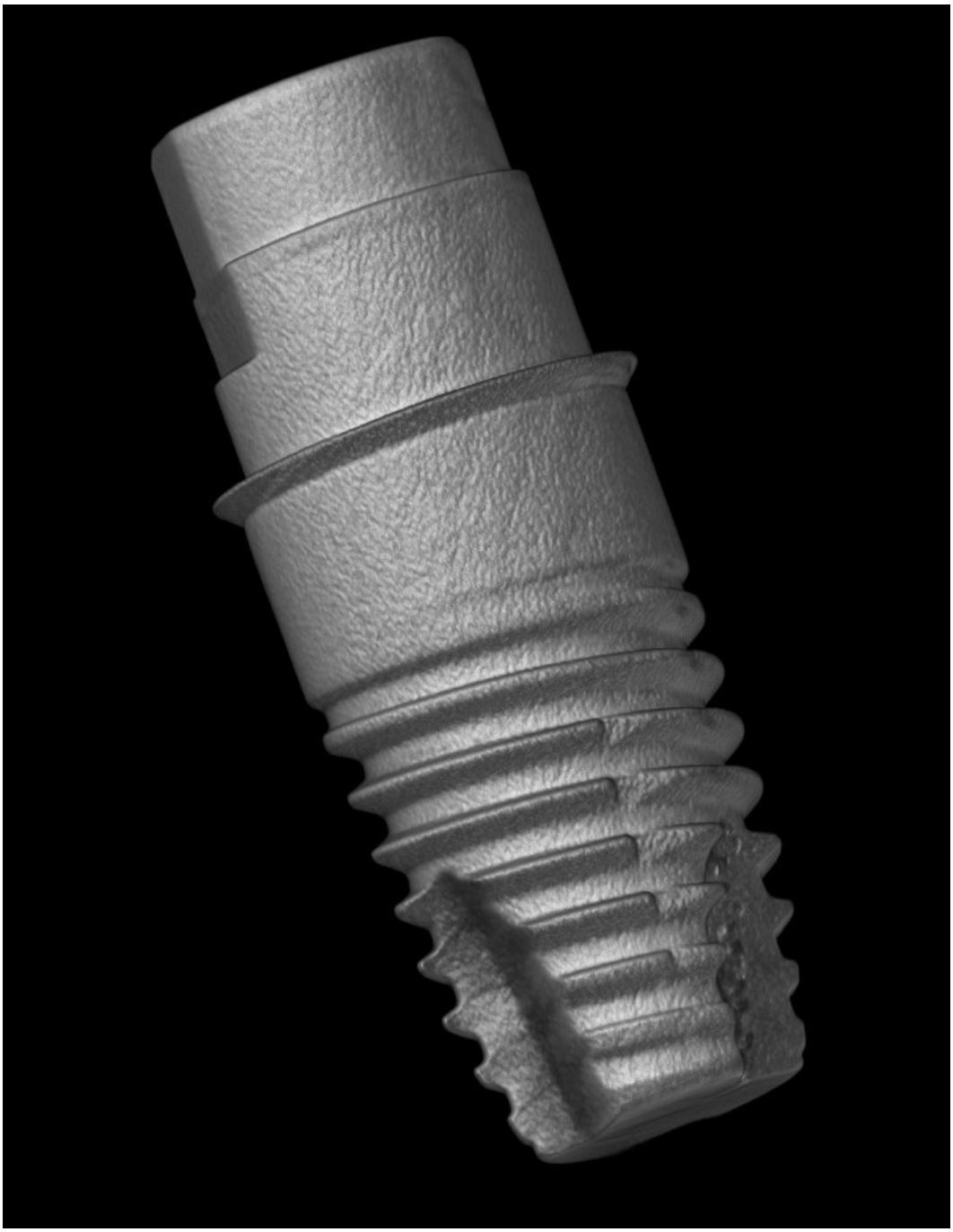


Figure 52: Specimen 3: External View 2 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

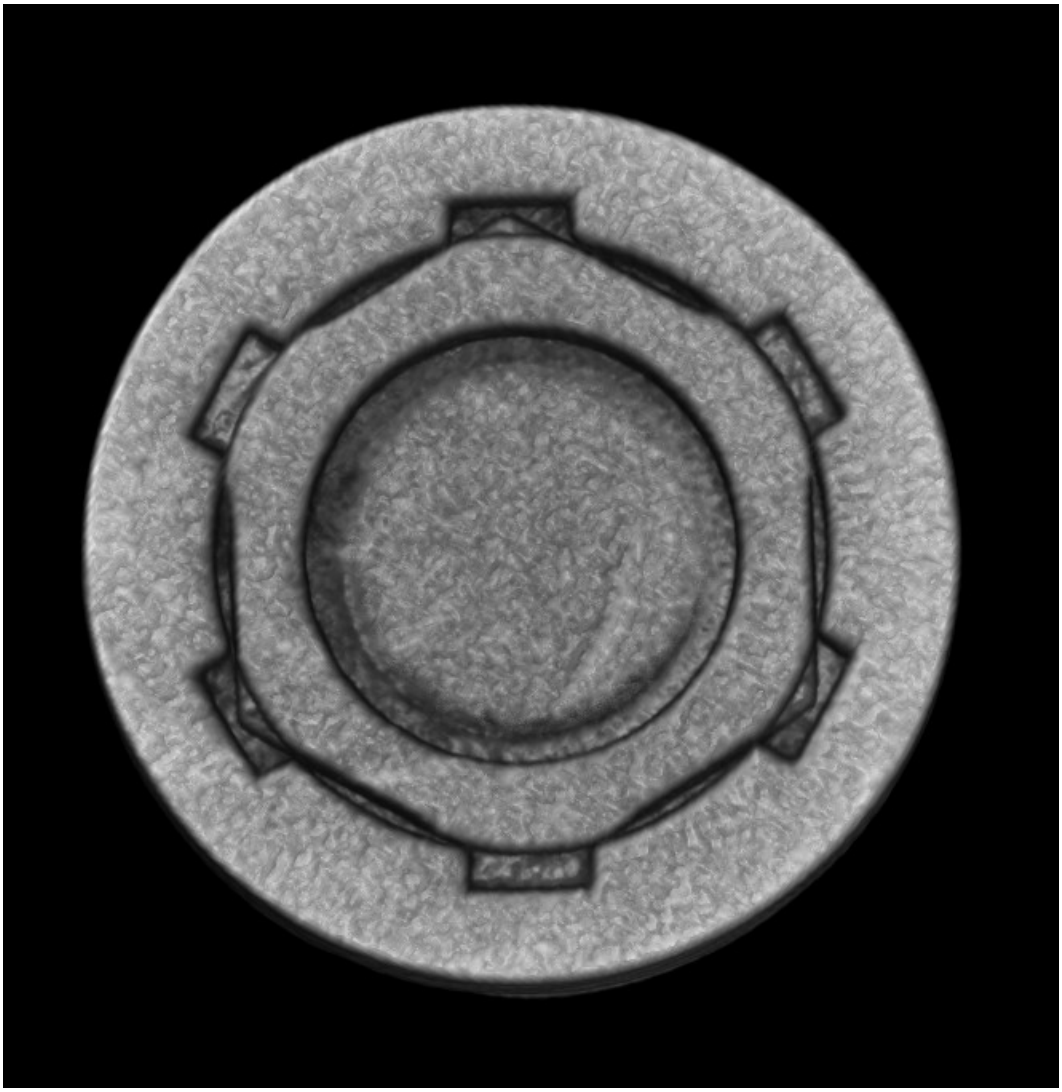


Figure 53: *Specimen 3: Cross sectional View 1 (high) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

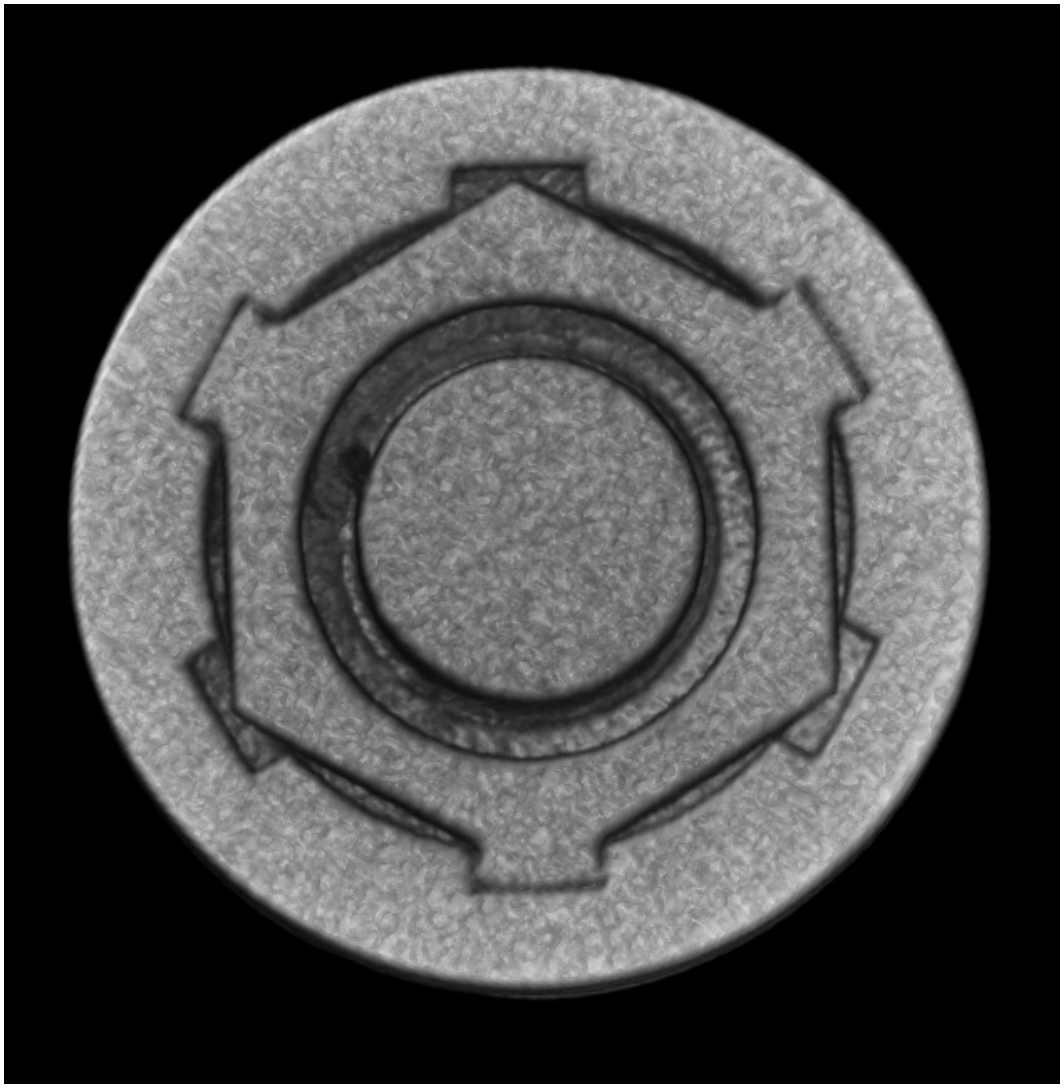


Figure 54: *Specimen 3: Cross sectional View 2 (mid) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

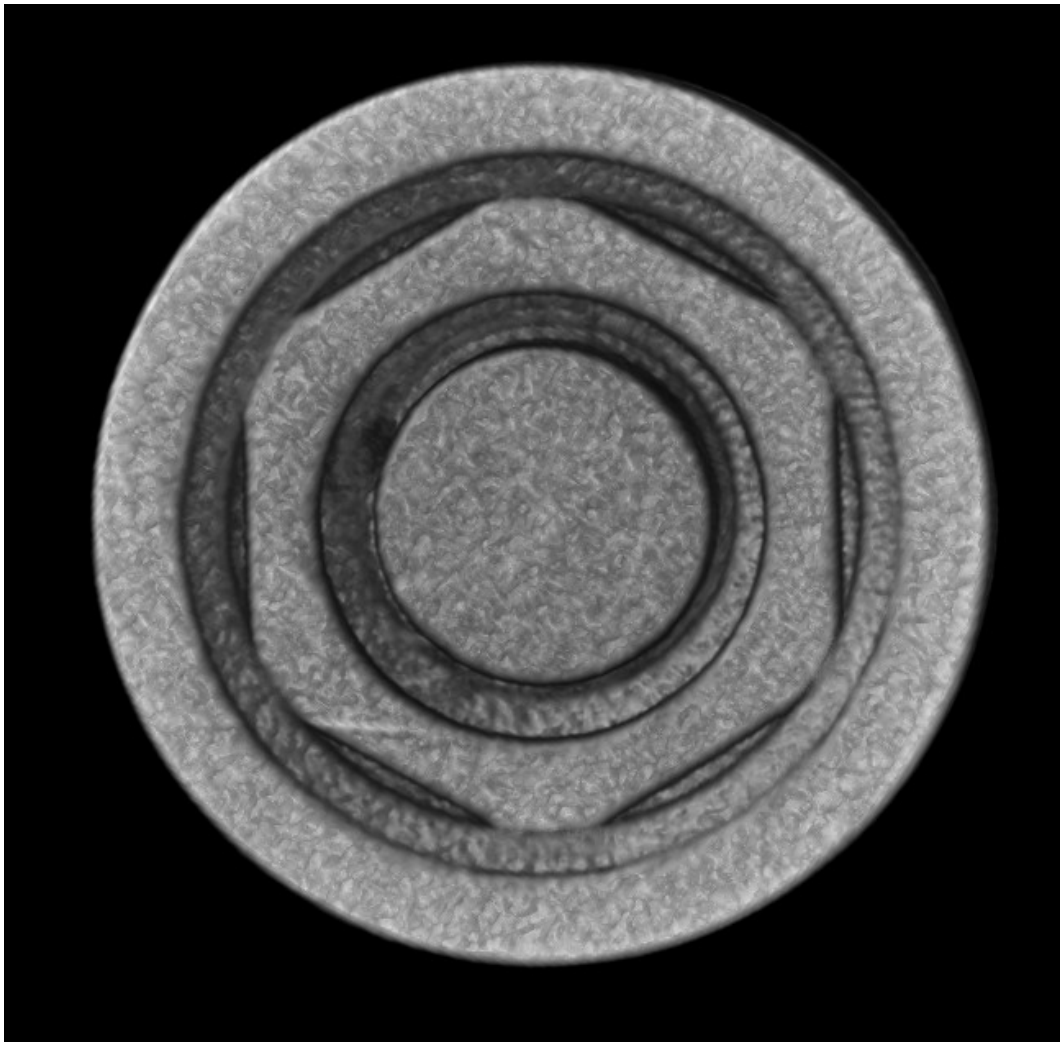


Figure 55: Specimen 3: Cross sectional View 3 (low) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

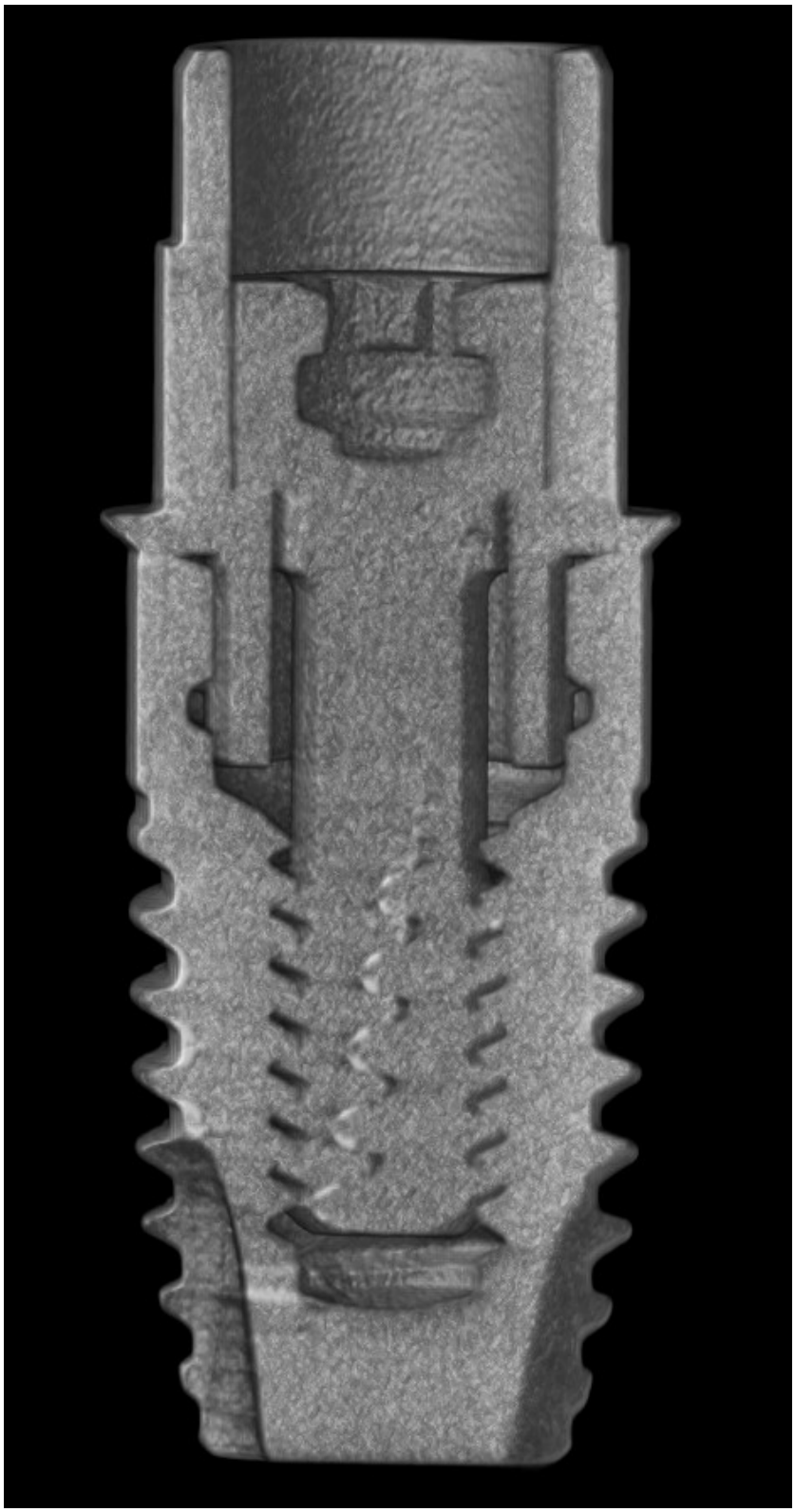


Figure 56: *Specimen 3: Coronal View 1 (anterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

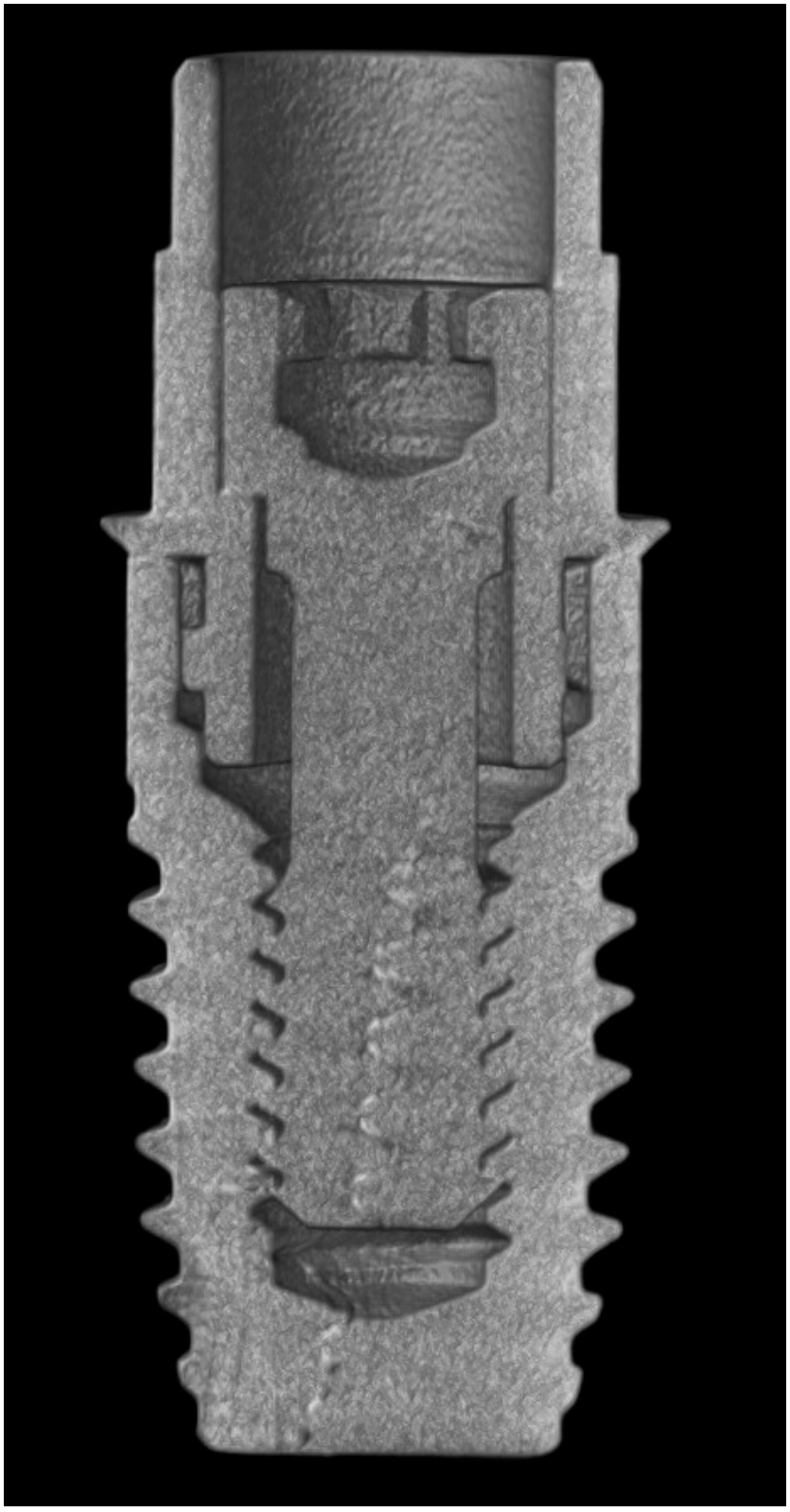


Figure 57: *Specimen 3: Coronal View 2 (midpoint) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

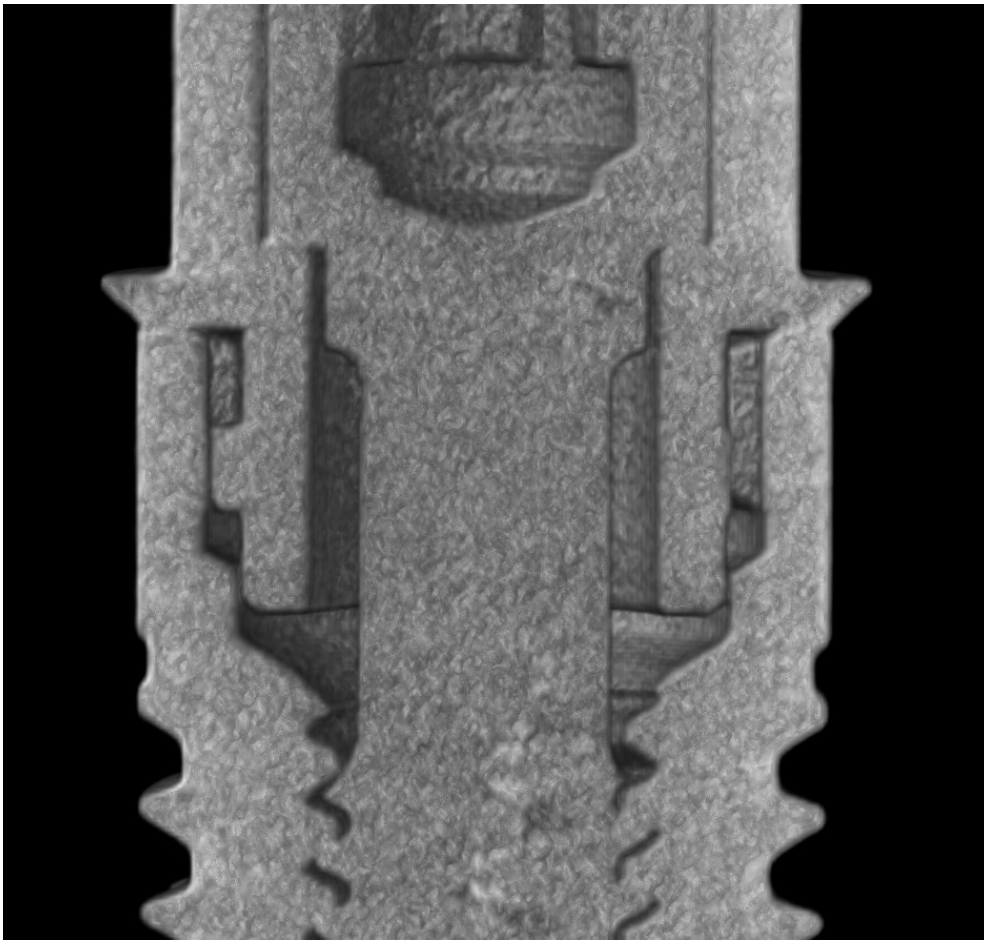


Figure 58: Specimen 3: Coronal View 3 (midpoint-zoom) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

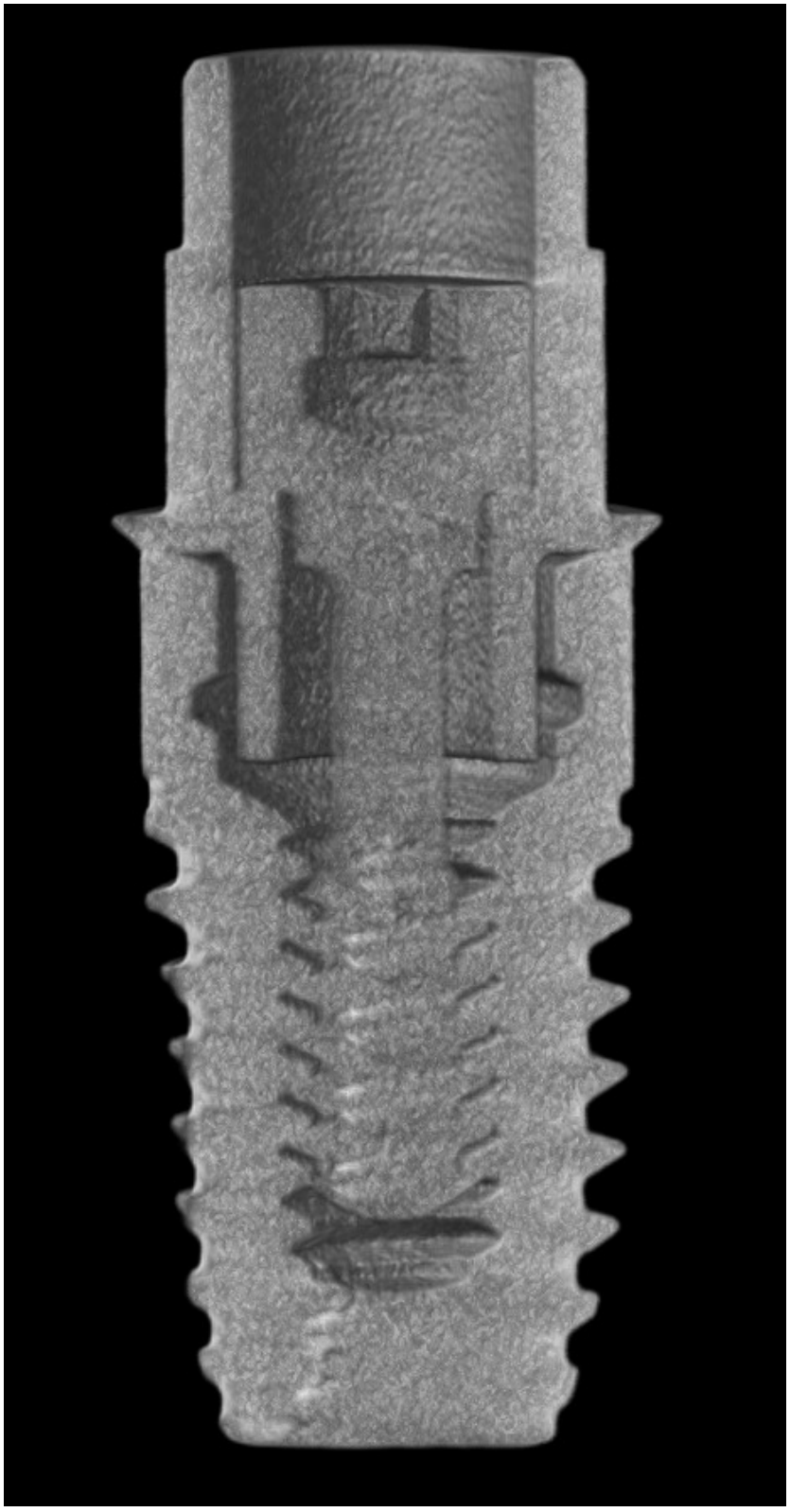


Figure 59: *Specimen 3: Coronal View 4 (posterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

Specimen 4

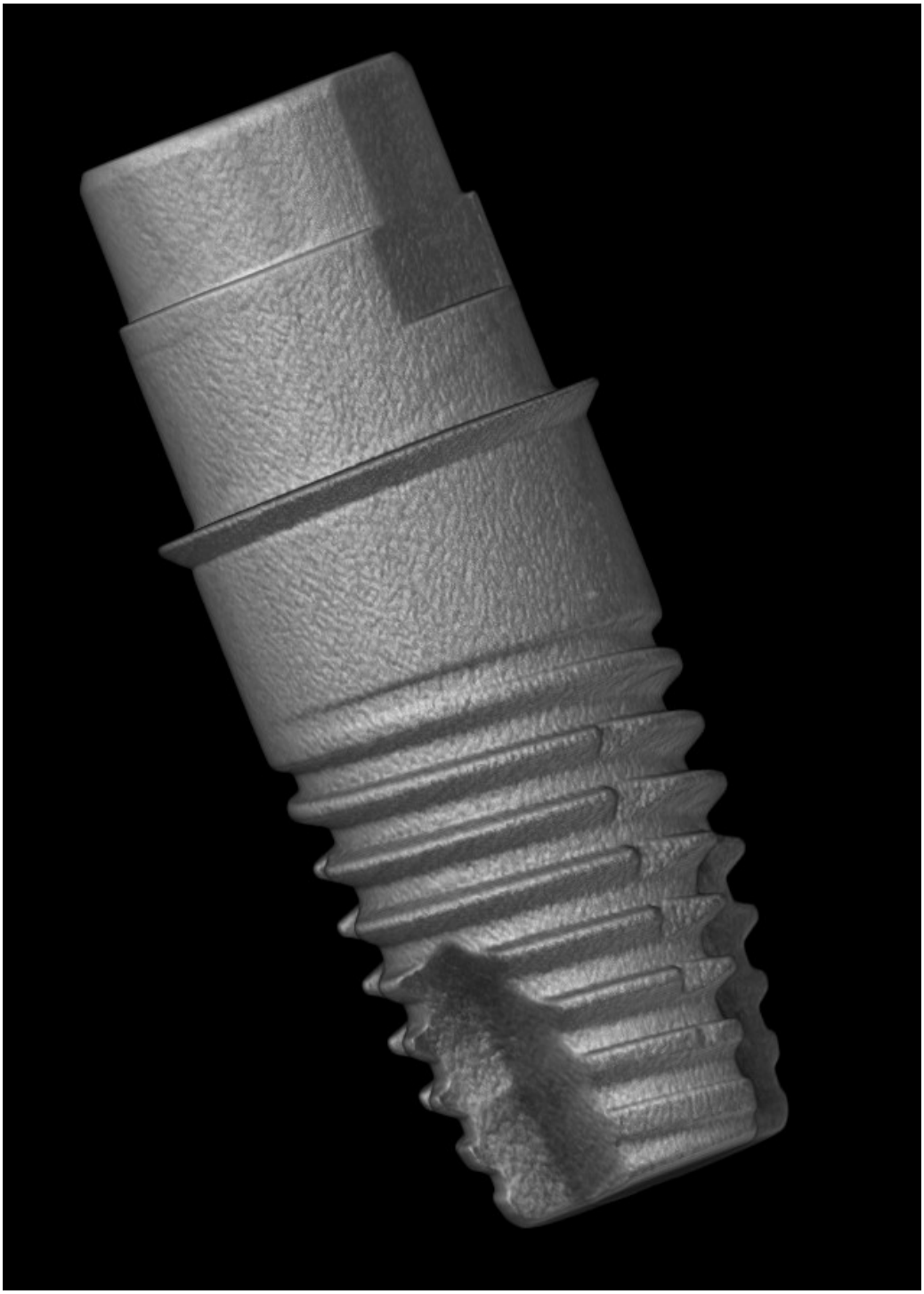


Figure 60: Specimen 4: External View 1 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

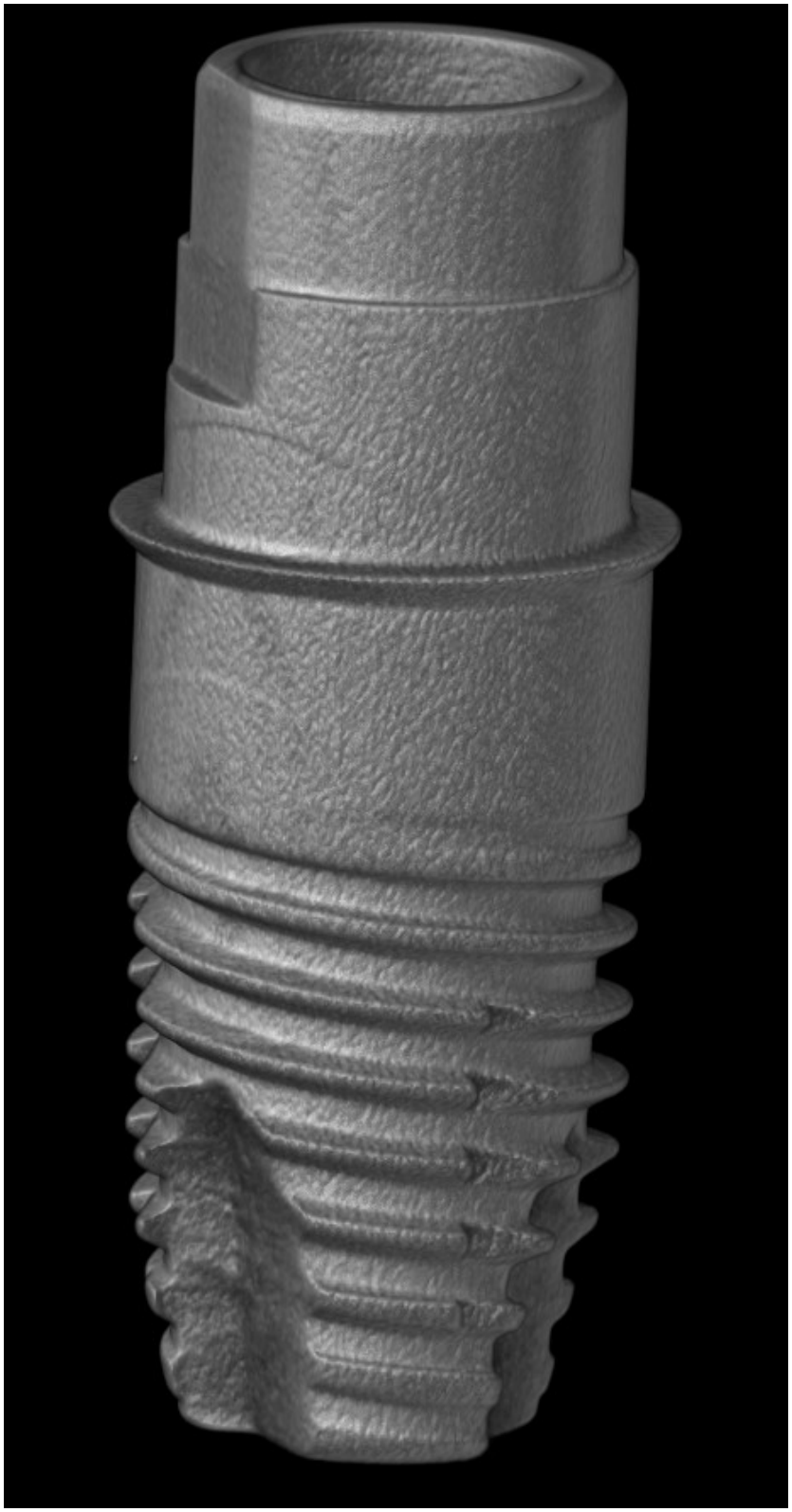


Figure 61: *Specimen 4: External View 2 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

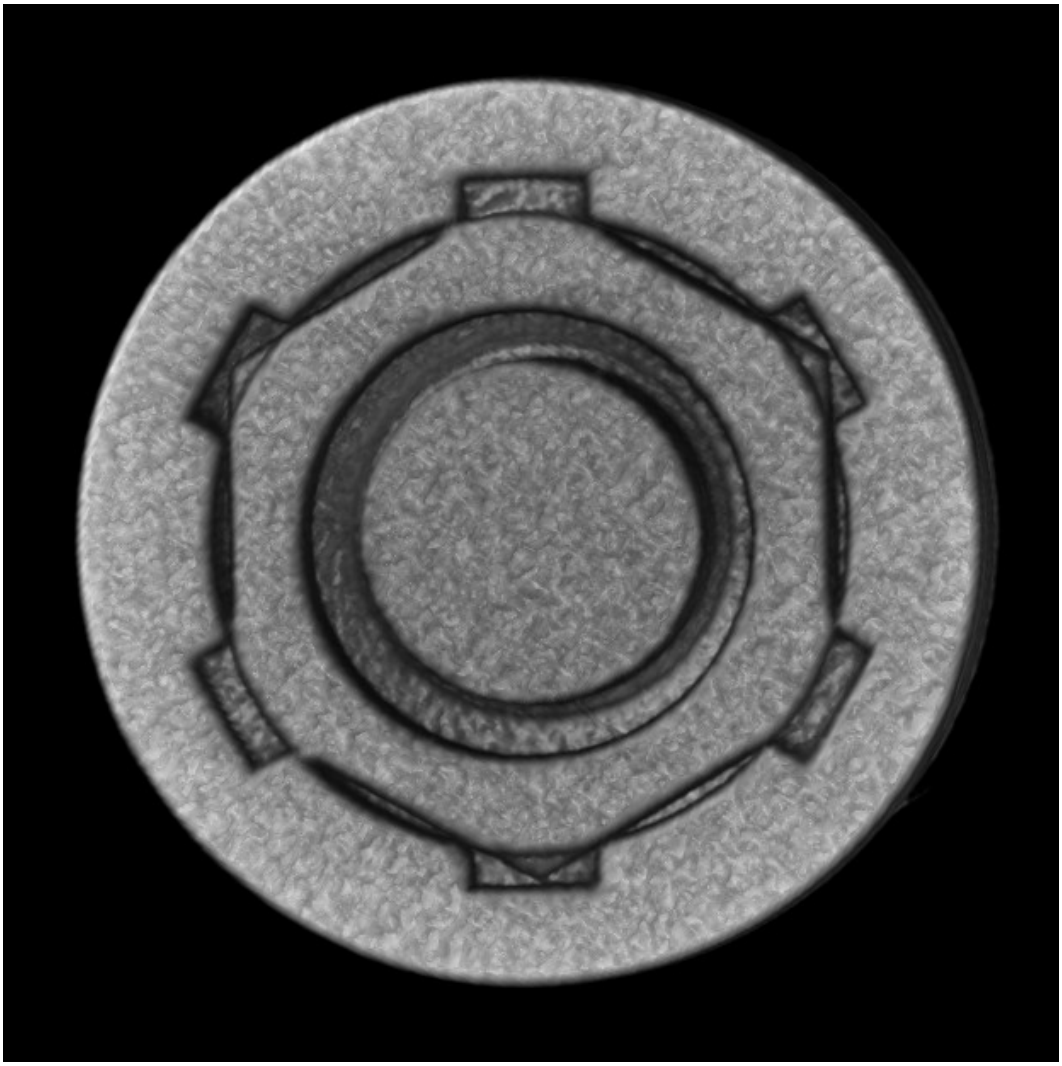


Figure 62: Specimen 4: Cross sectional View 1 (high) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

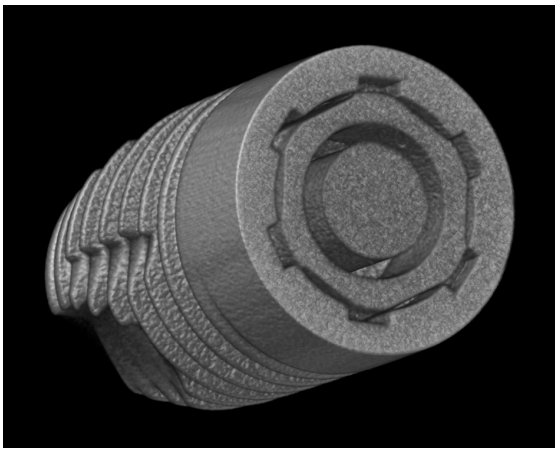


Figure 63: Specimen 4: Cross sectional View 1a (high - adjacent) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

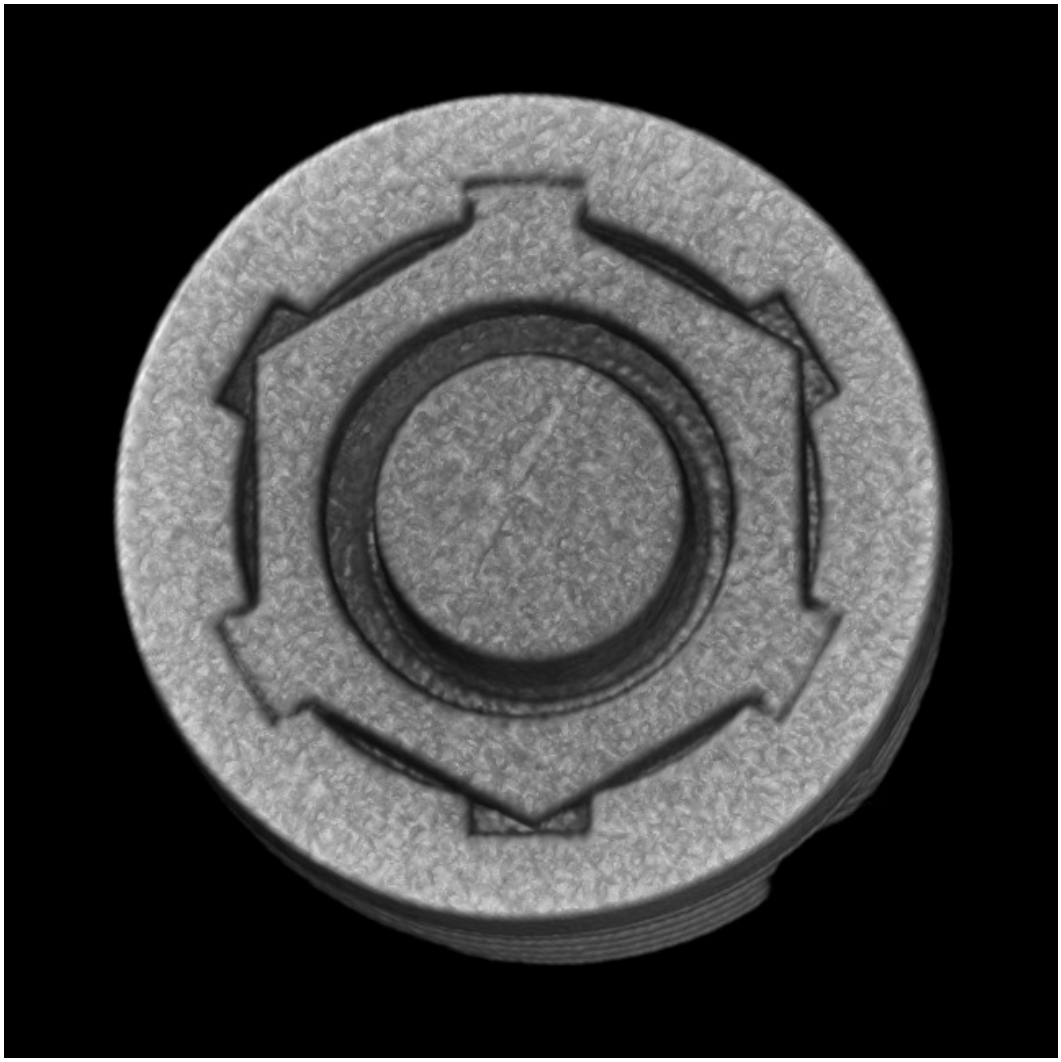


Figure 64: *Specimen 4: Cross sectional View 2 (mid) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

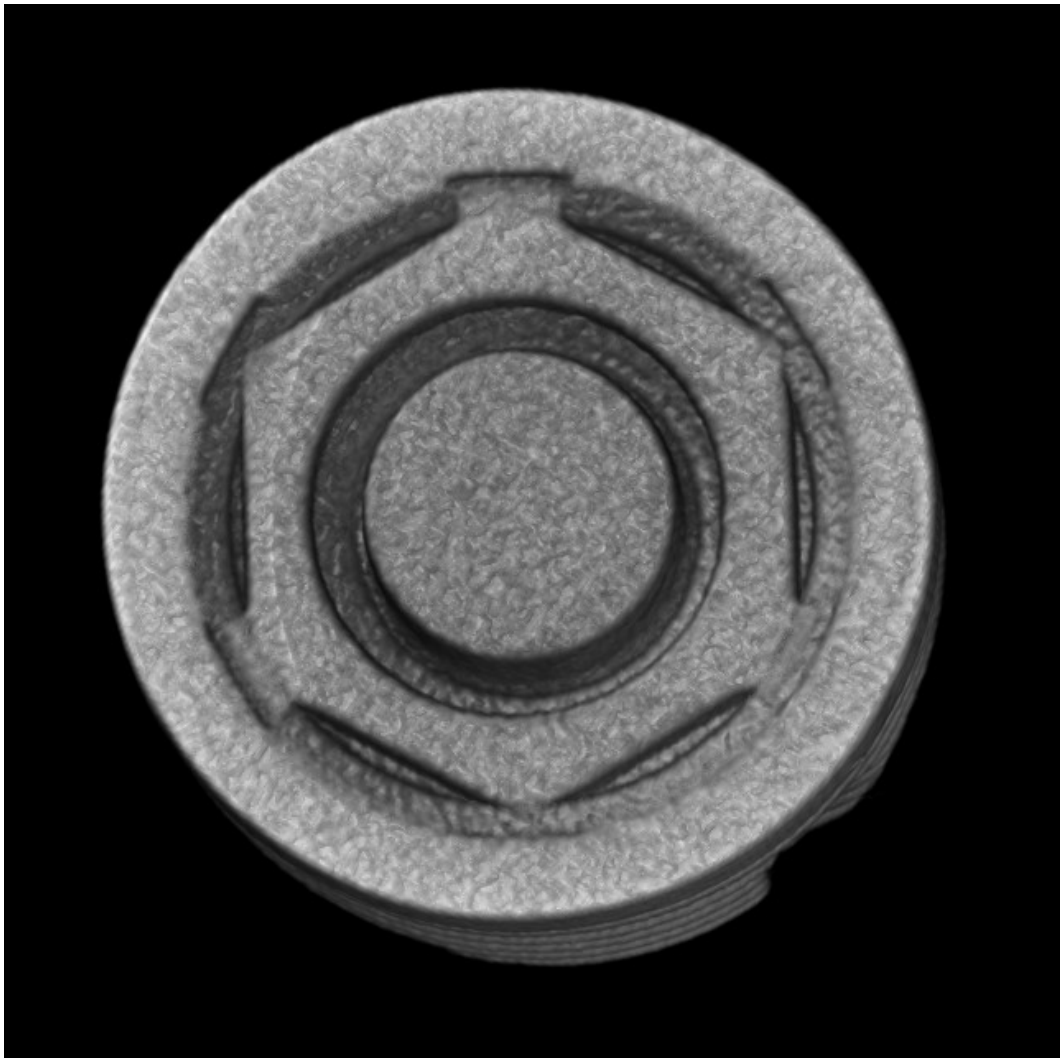


Figure 65: Specimen 4: Cross sectional View 3 (low) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

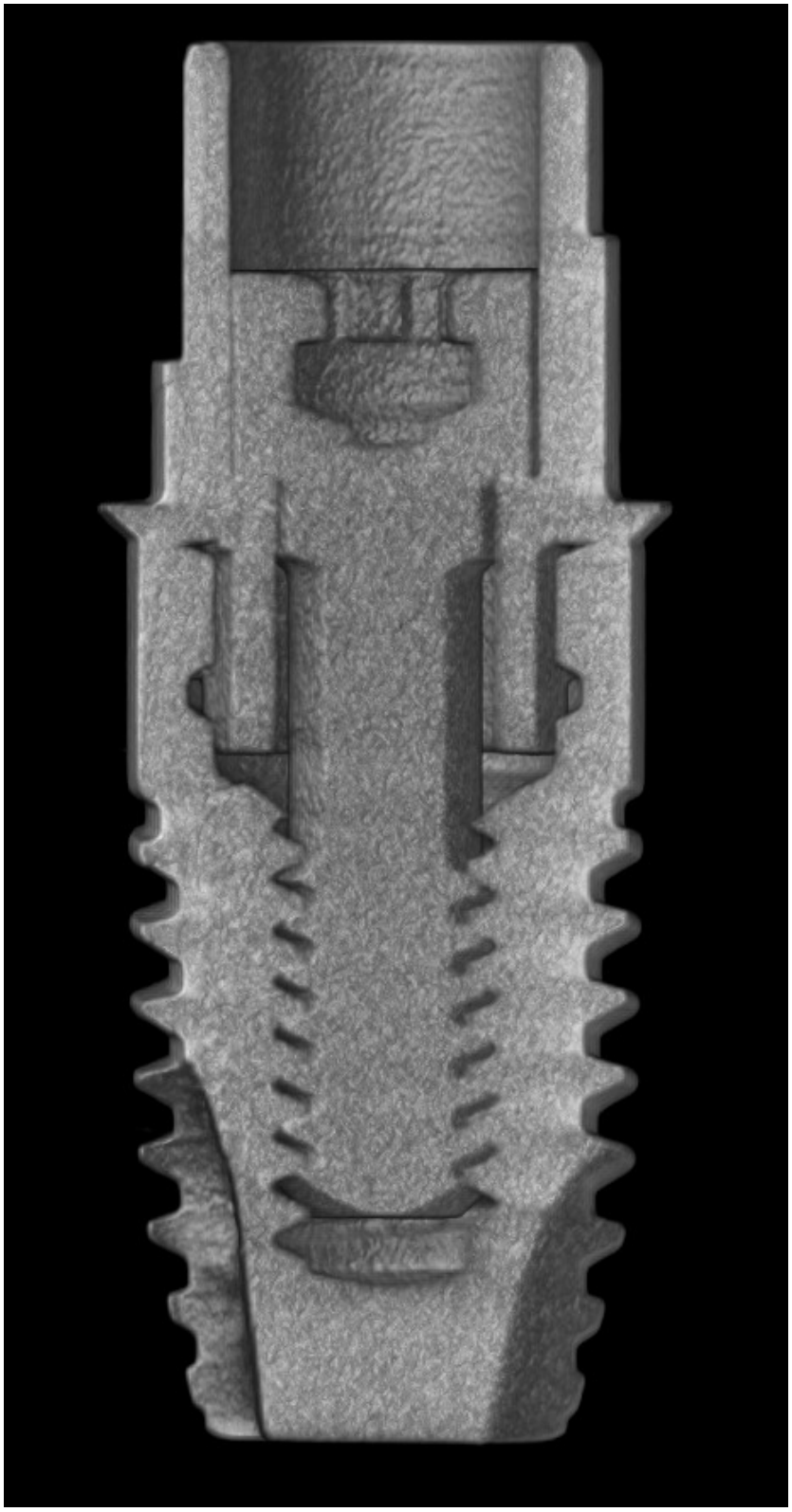


Figure 66: Specimen 4: Coronal View 1 (anterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

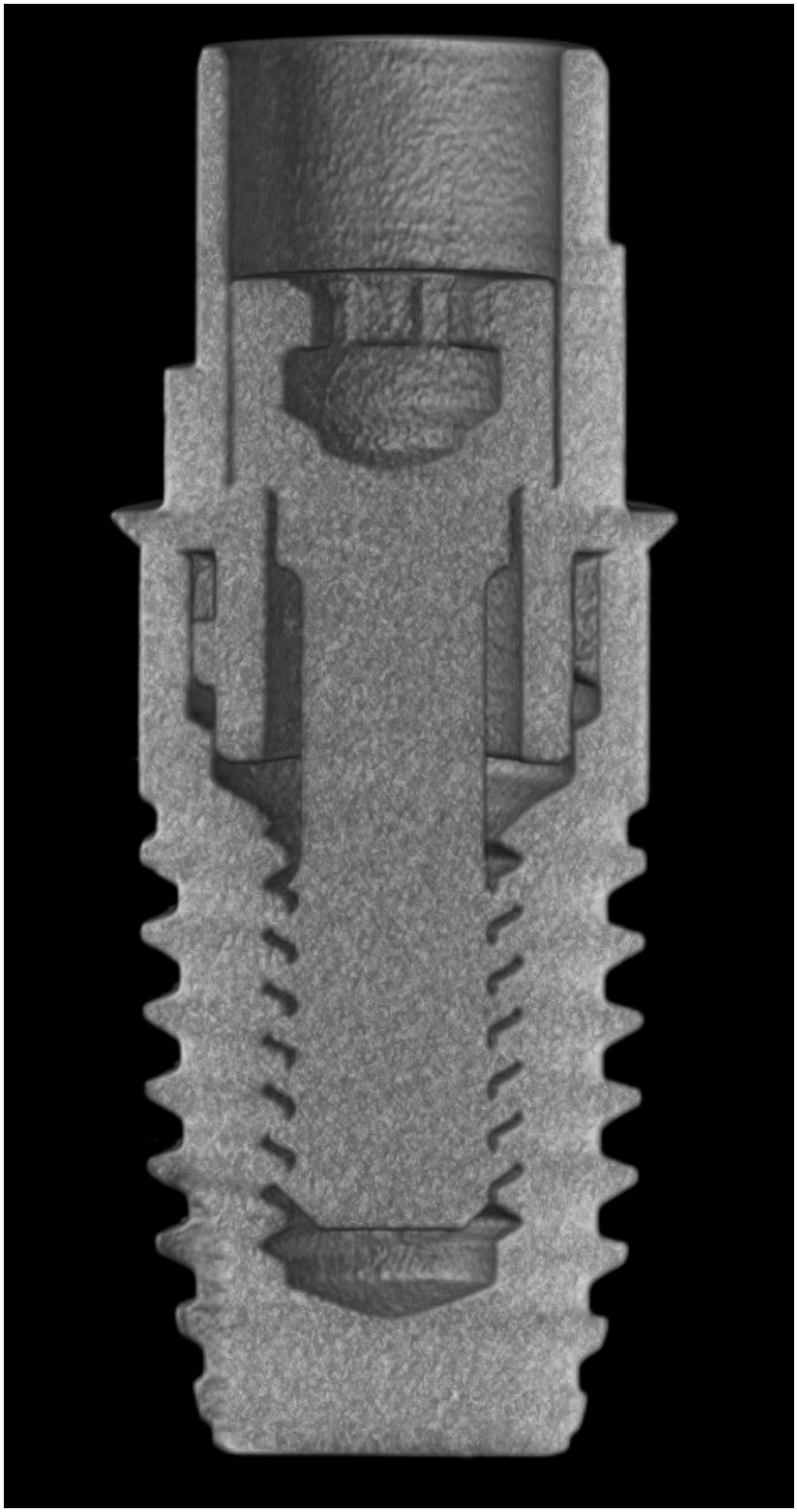


Figure 67: *Specimen 4: Coronal View 1 (midpoint slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

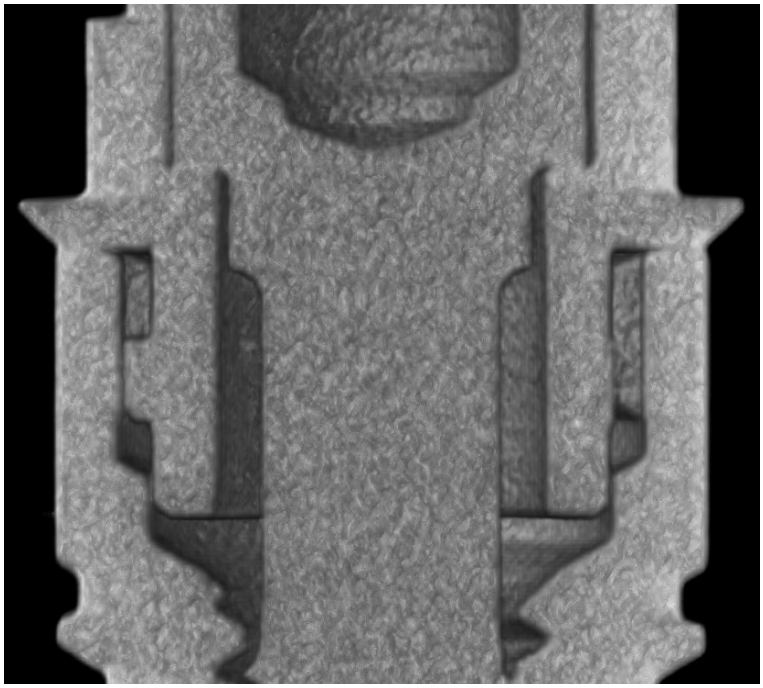


Figure 68: *Specimen 4: Coronal View 1a (midpoint zoom) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

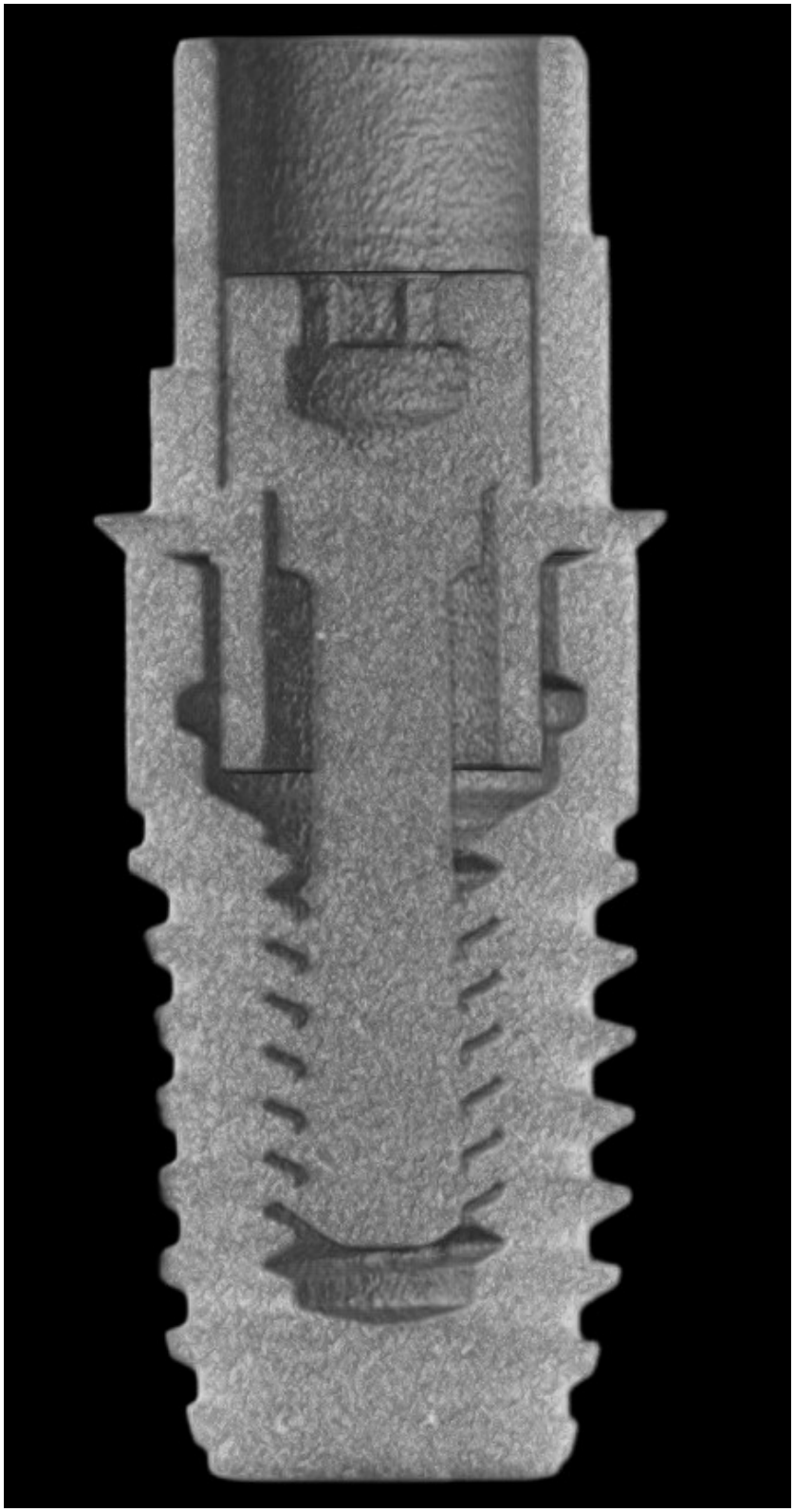


Figure 69: *Specimen 4: Coronal View 1 (posterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

Specimen 5

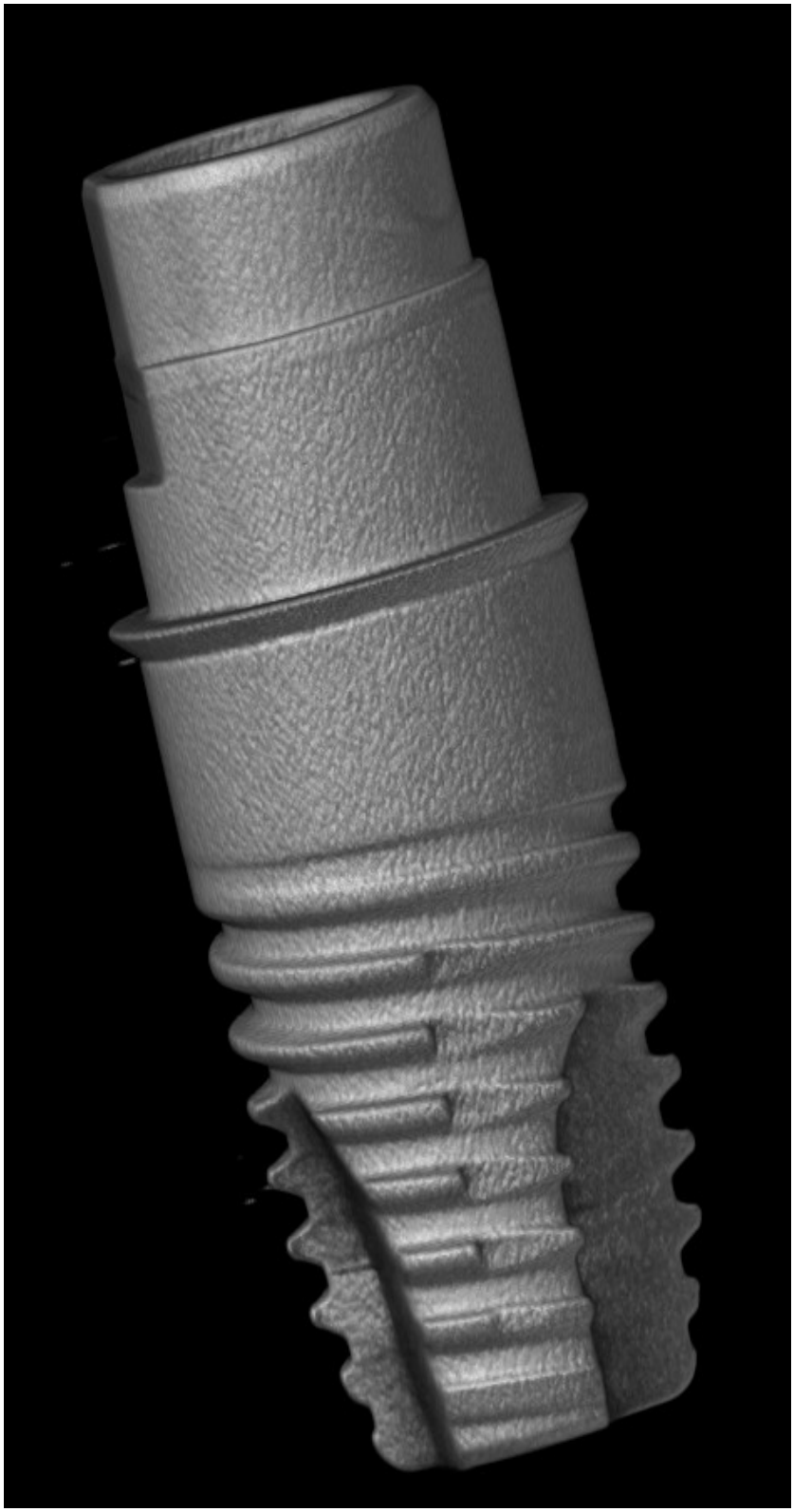


Figure 70: Specimen 5: External View 1 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

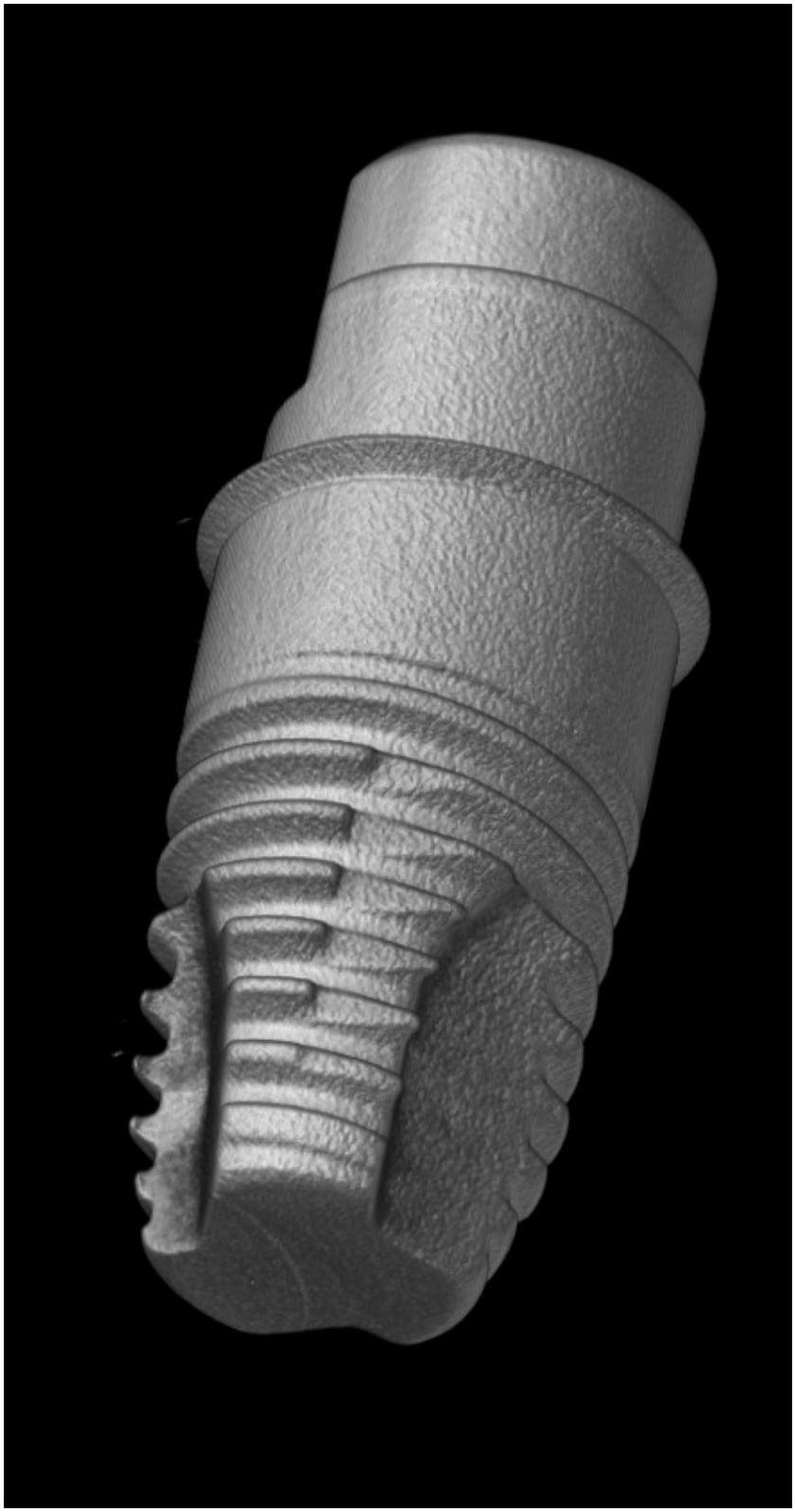


Figure 71: Specimen 5: External View 2 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

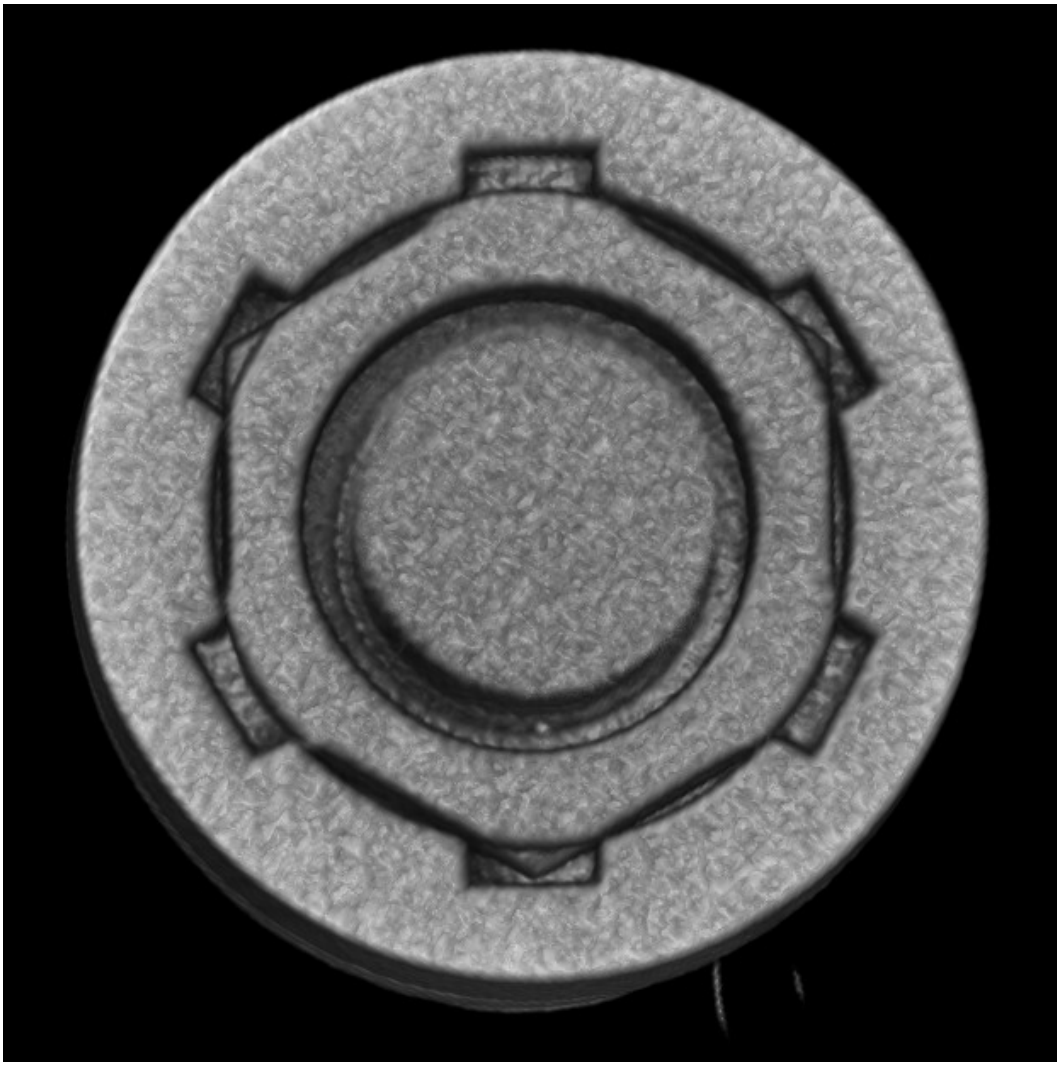


Figure 72: Specimen 5: Cross sectional View 1 (high) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

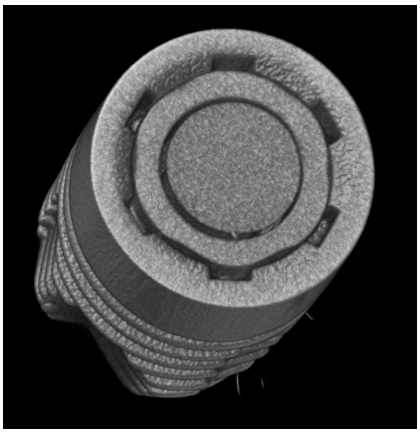


Figure 73: Specimen 5: Cross sectional View 1a (high - adjacent) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

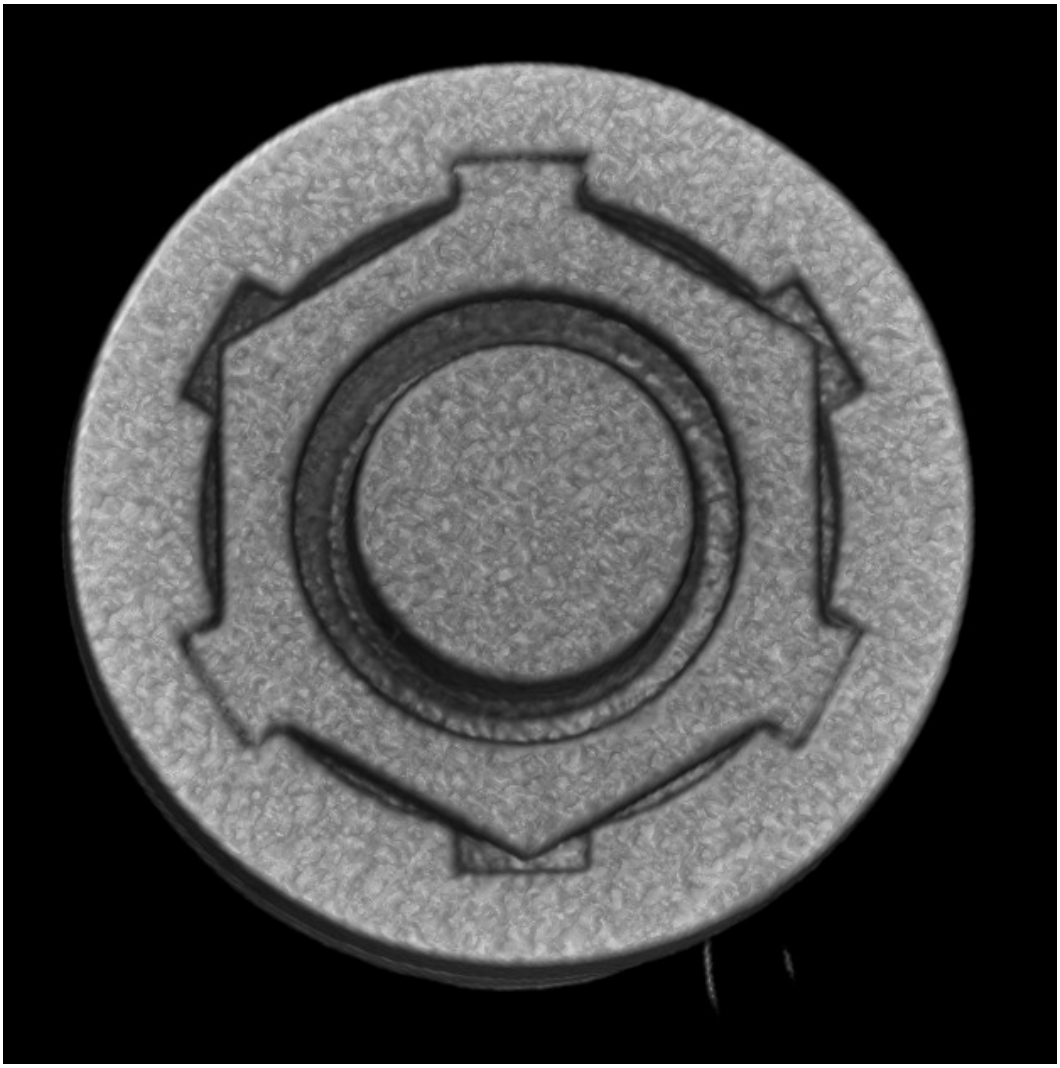


Figure 74: Specimen 5: Cross sectional View 2 (midpoint) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

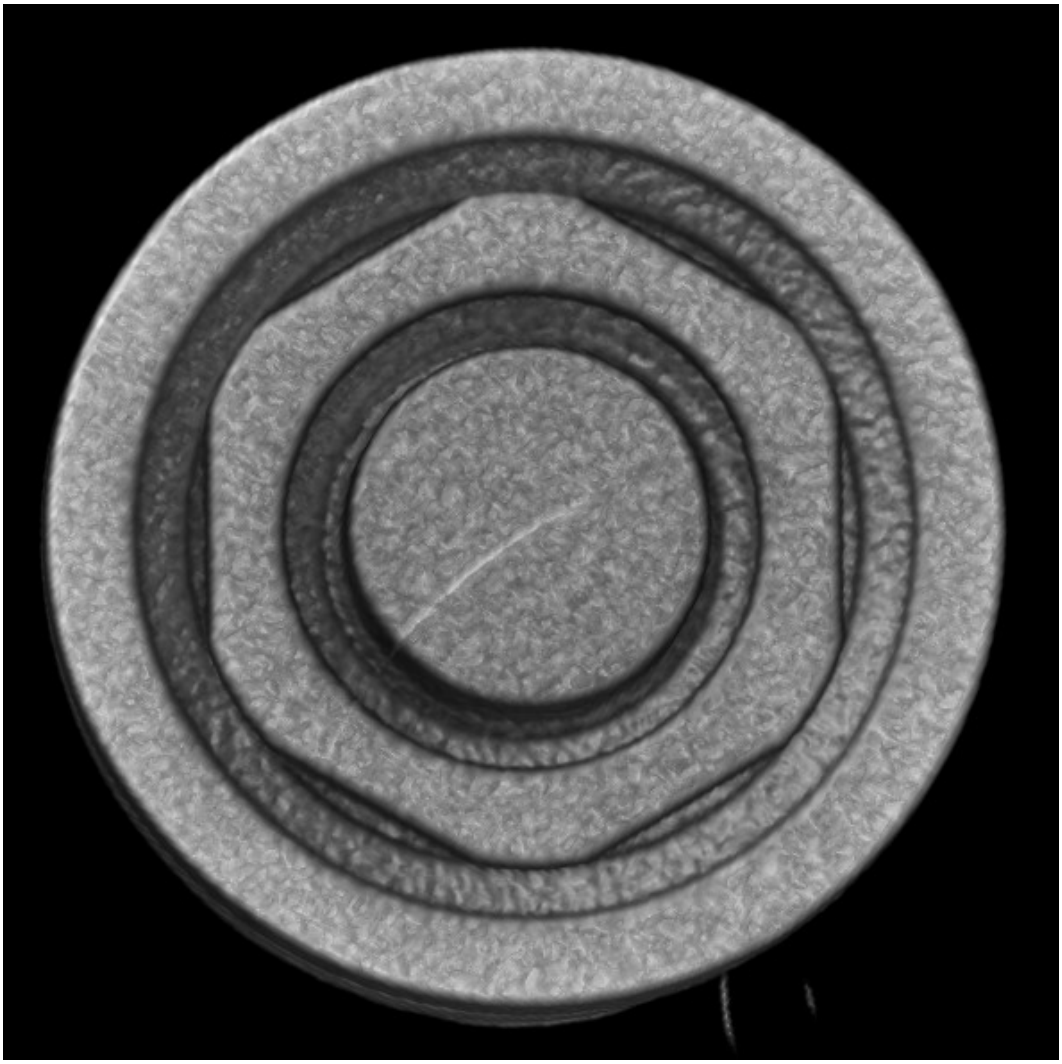


Figure 75: Specimen 5: Cross sectional View 3 (low) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

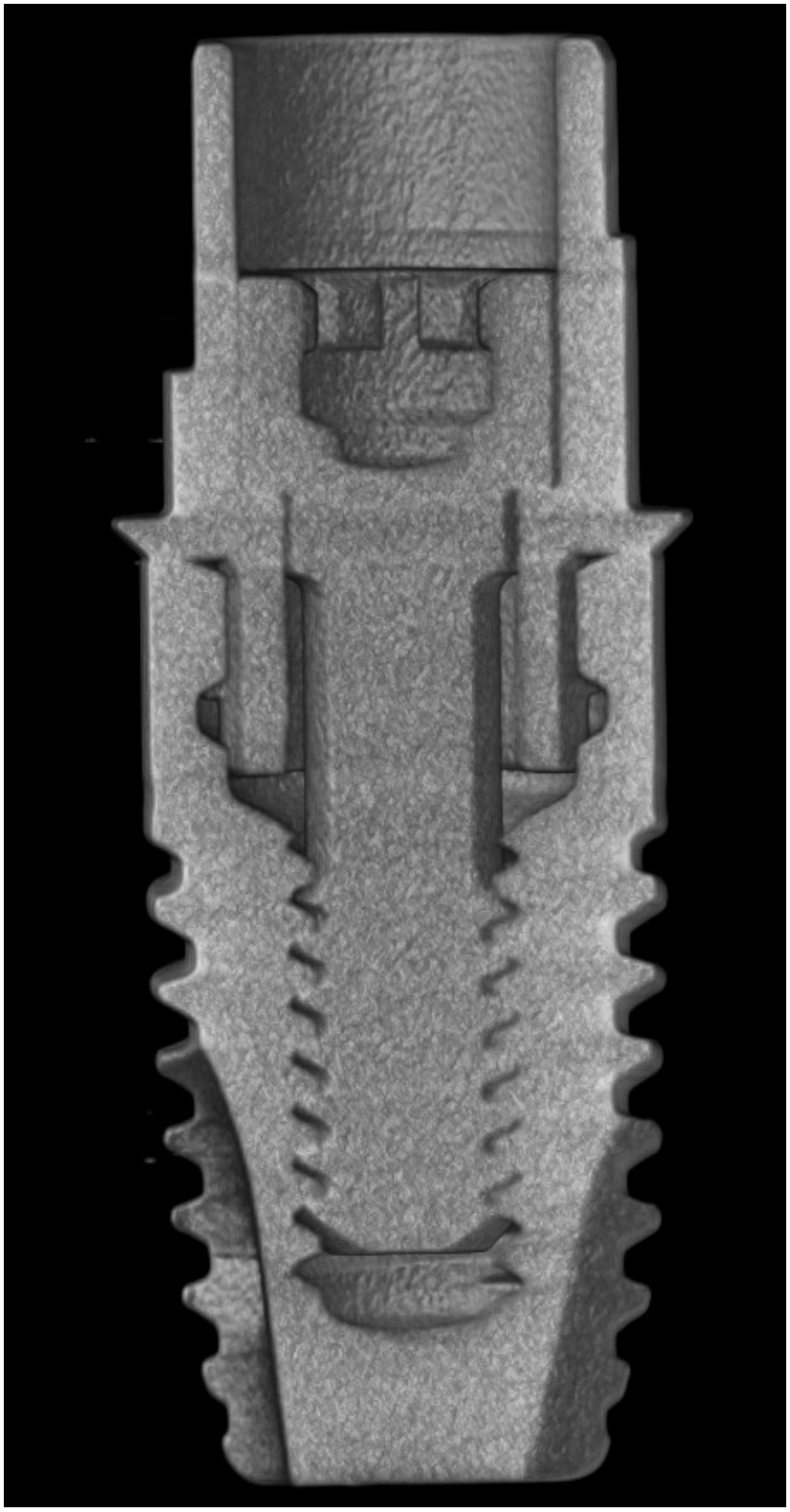


Figure 76: *Specimen 5: Coronal View 1 (anterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

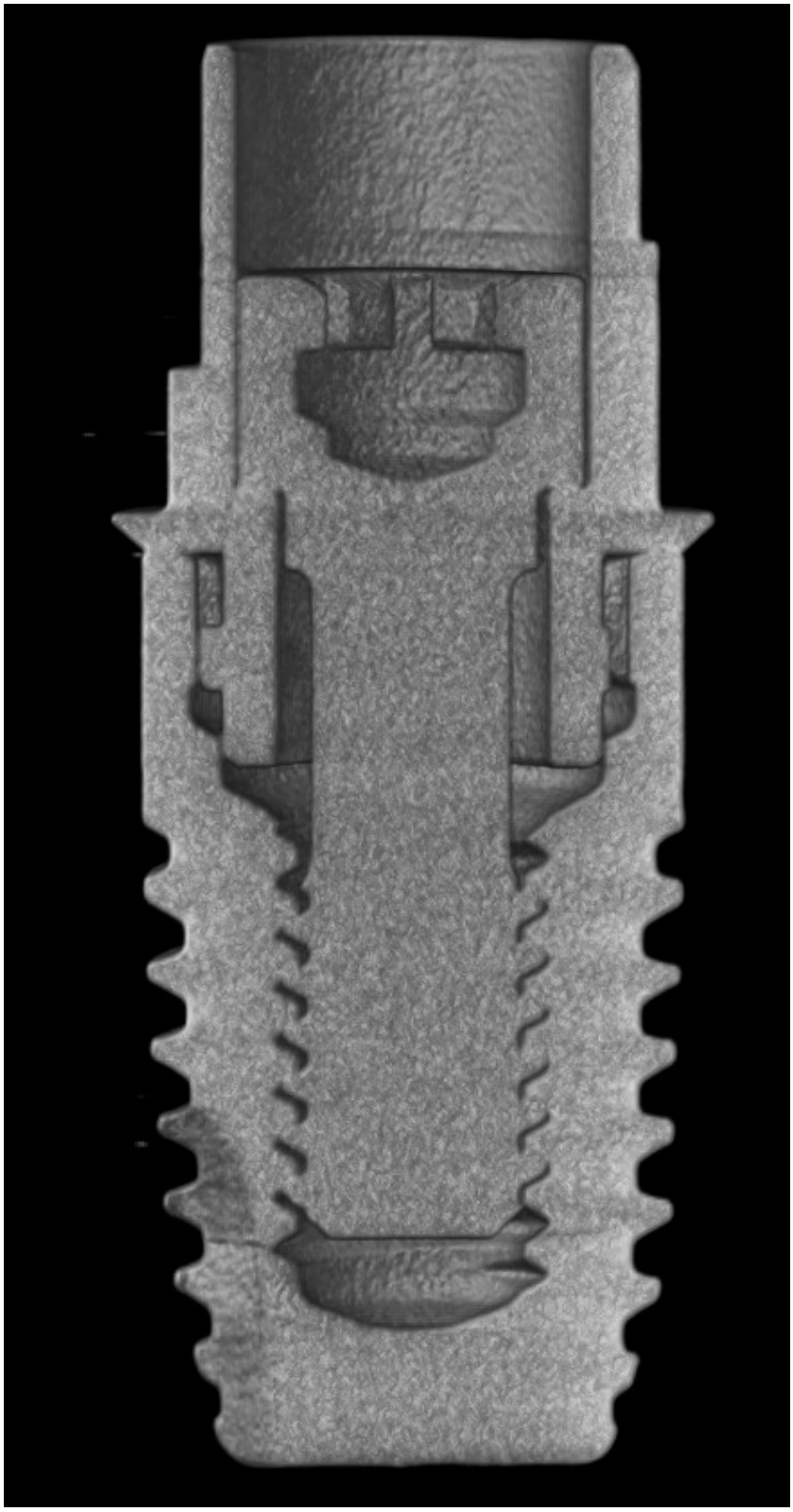


Figure 77: *Specimen 5: Coronal View 2 (midpoint slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

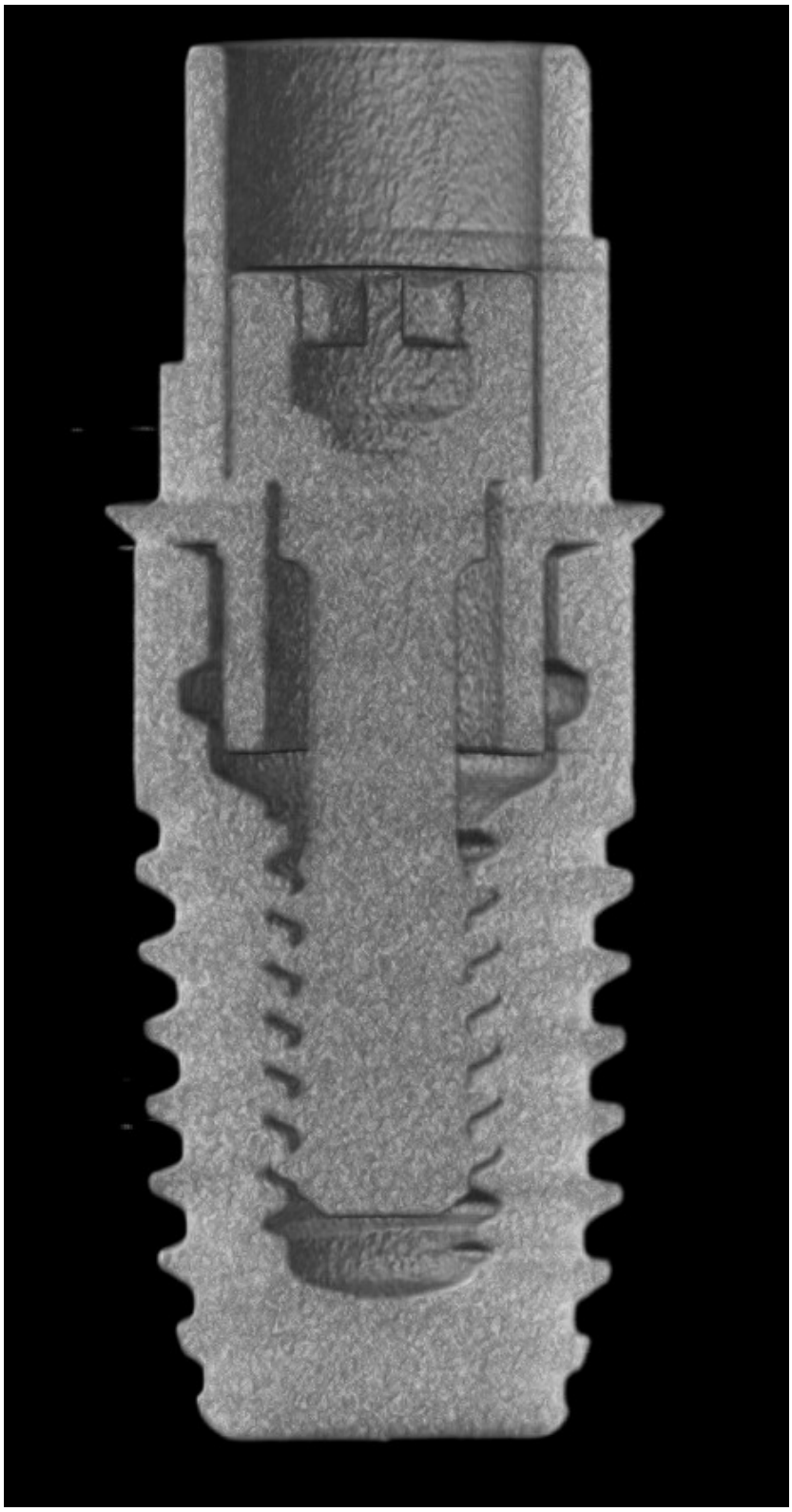


Figure 78: *Specimen 5: Coronal View 3 (posterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

Specimen 6

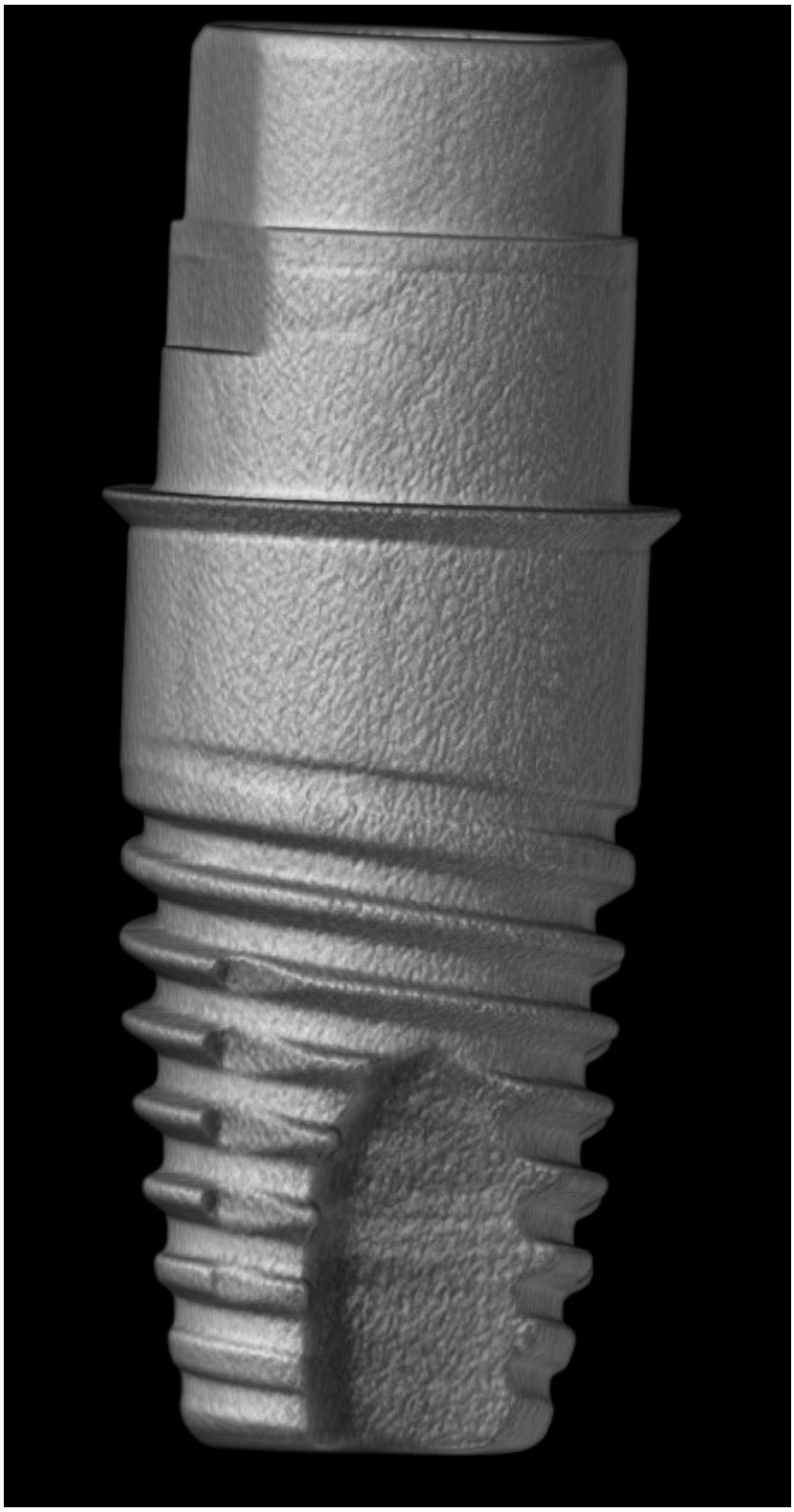


Figure 79: *Specimen 6: External View 1 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

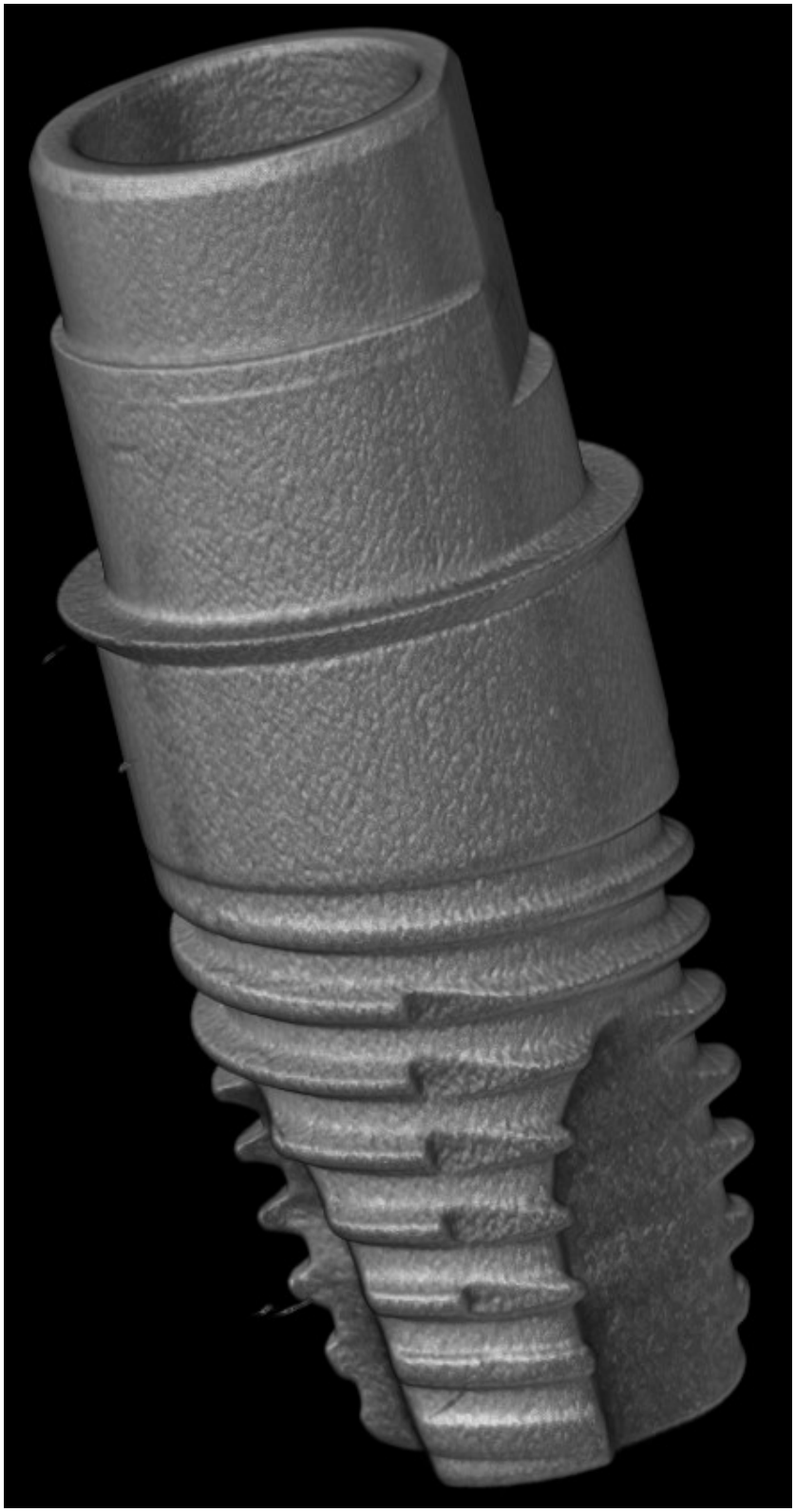


Figure 80: *Specimen 6: External View 2 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

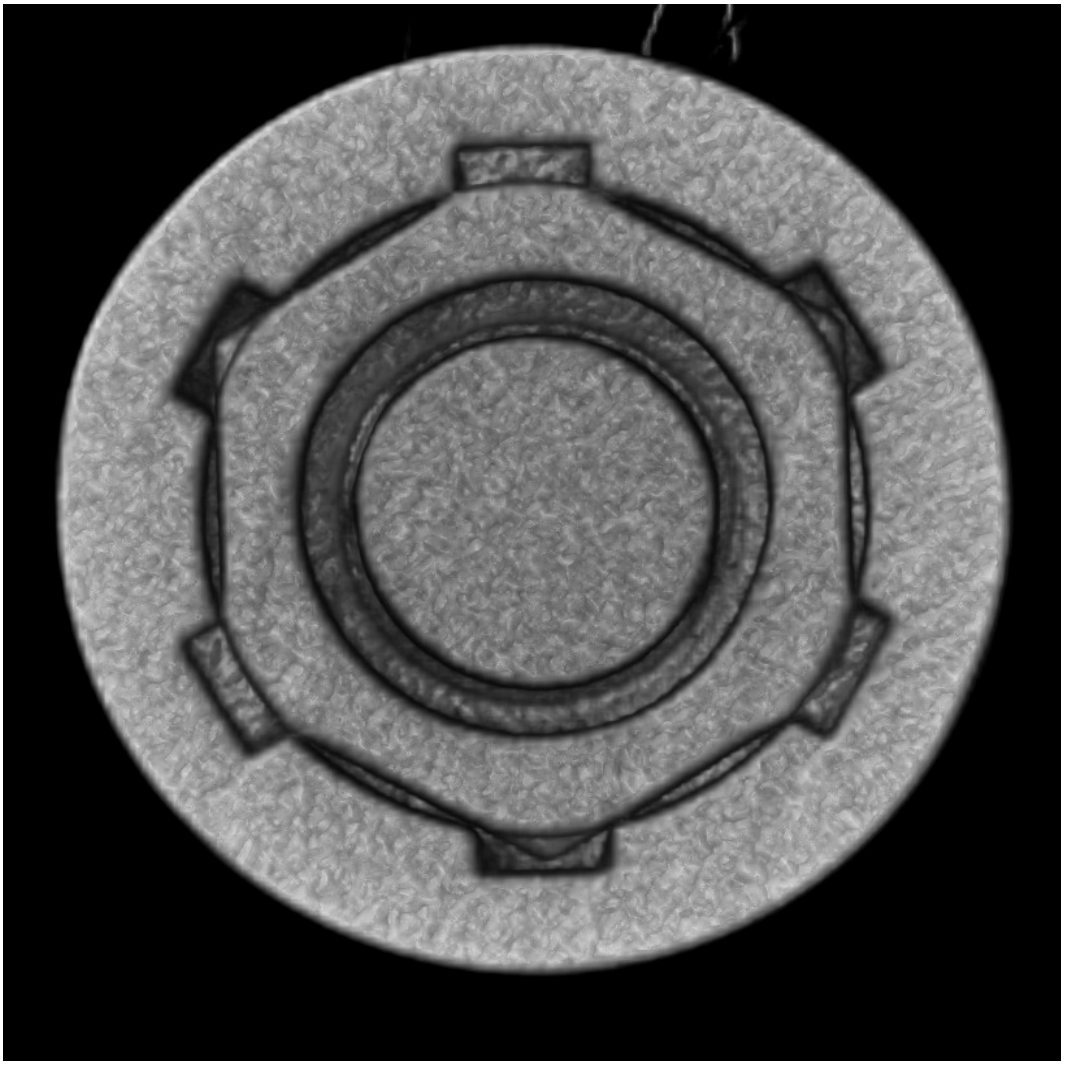


Figure 81: Specimen 6: Cross sectional View 1 (high) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

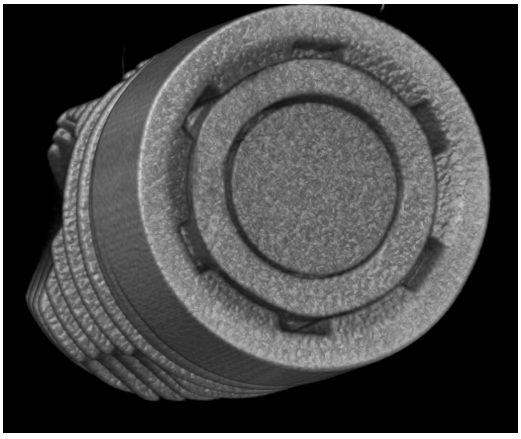


Figure 82: Specimen 6: Cross sectional View 1a (high - adjacent) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

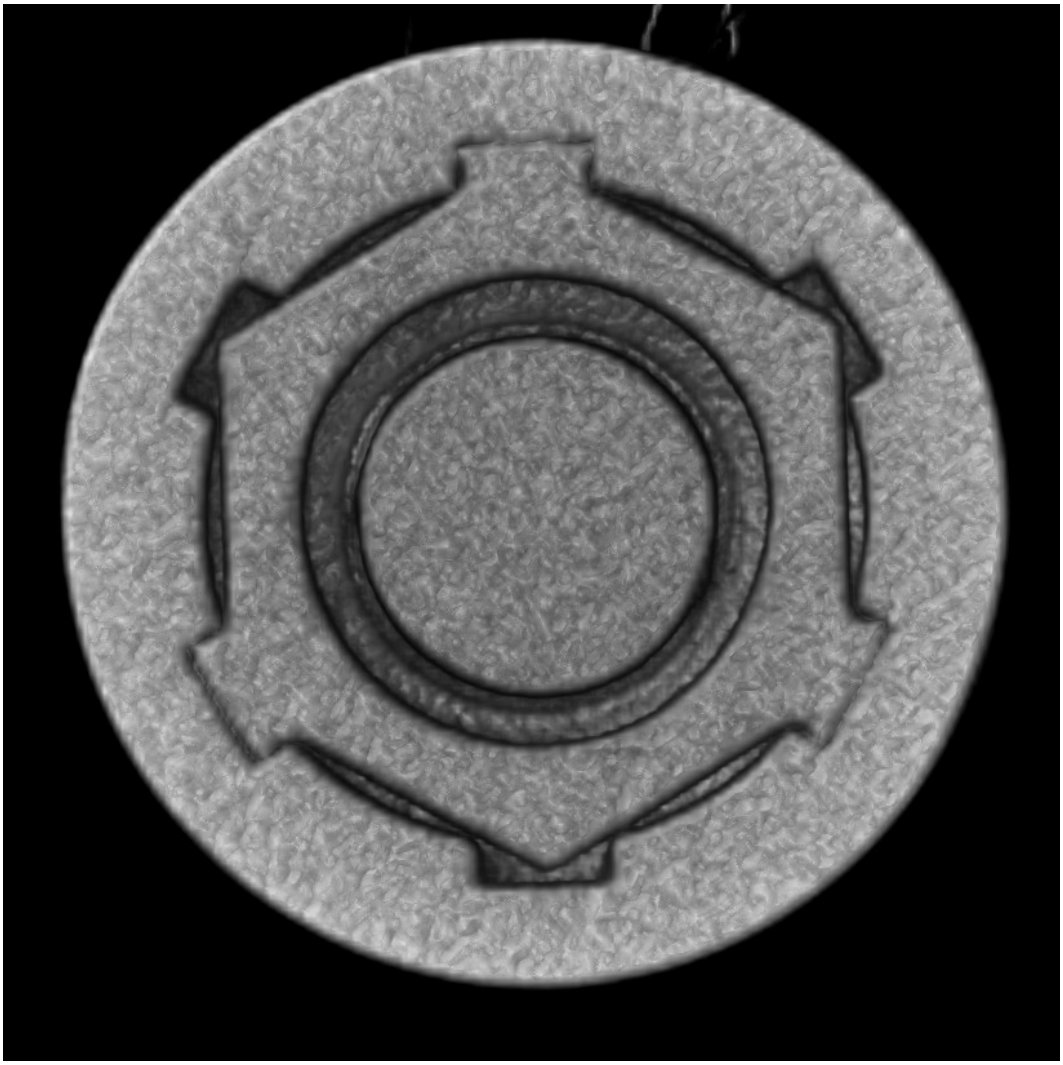


Figure 83: Specimen 6: Cross sectional View 2 (midpoint slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

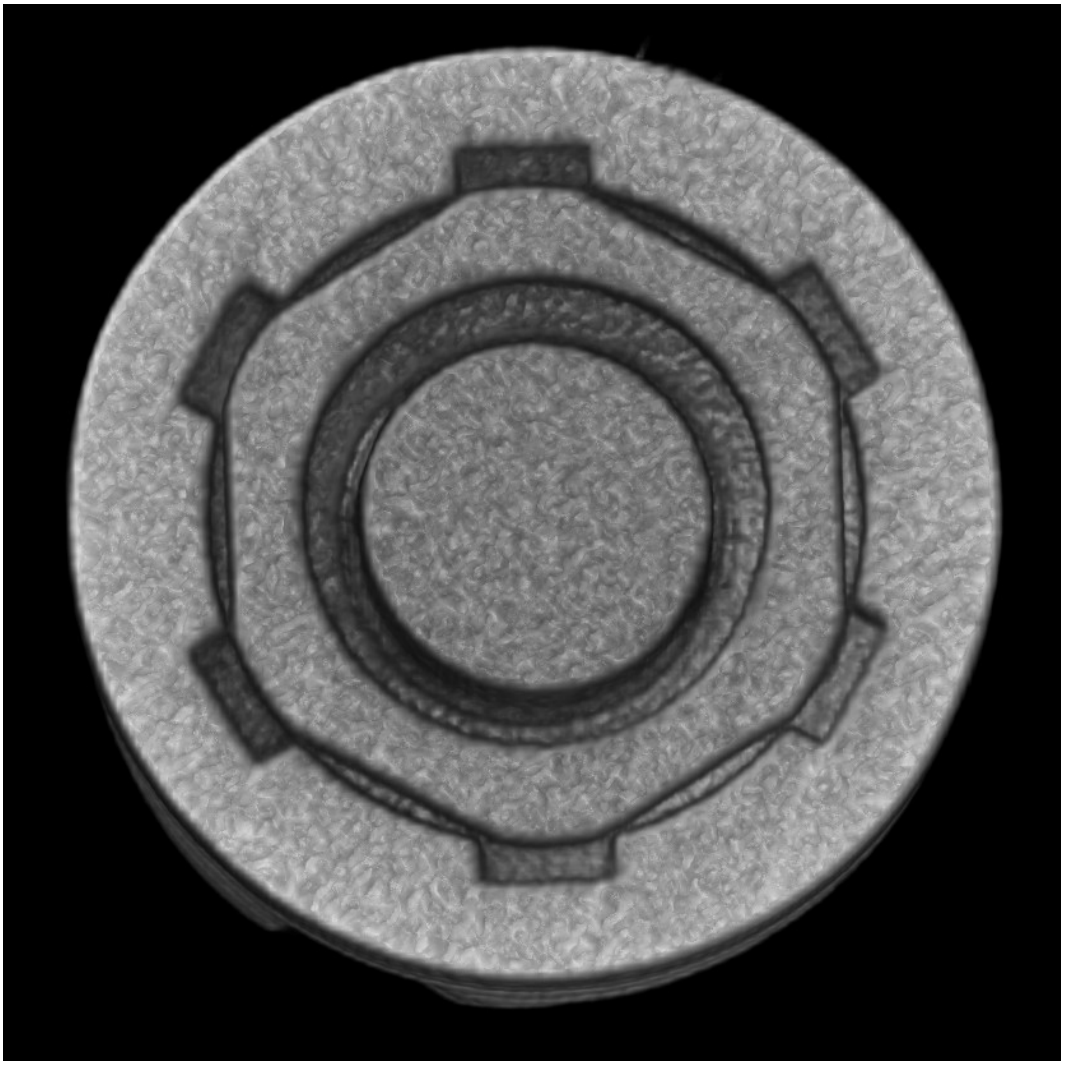


Figure 84: Specimen 6: Cross sectional View 3 (low slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

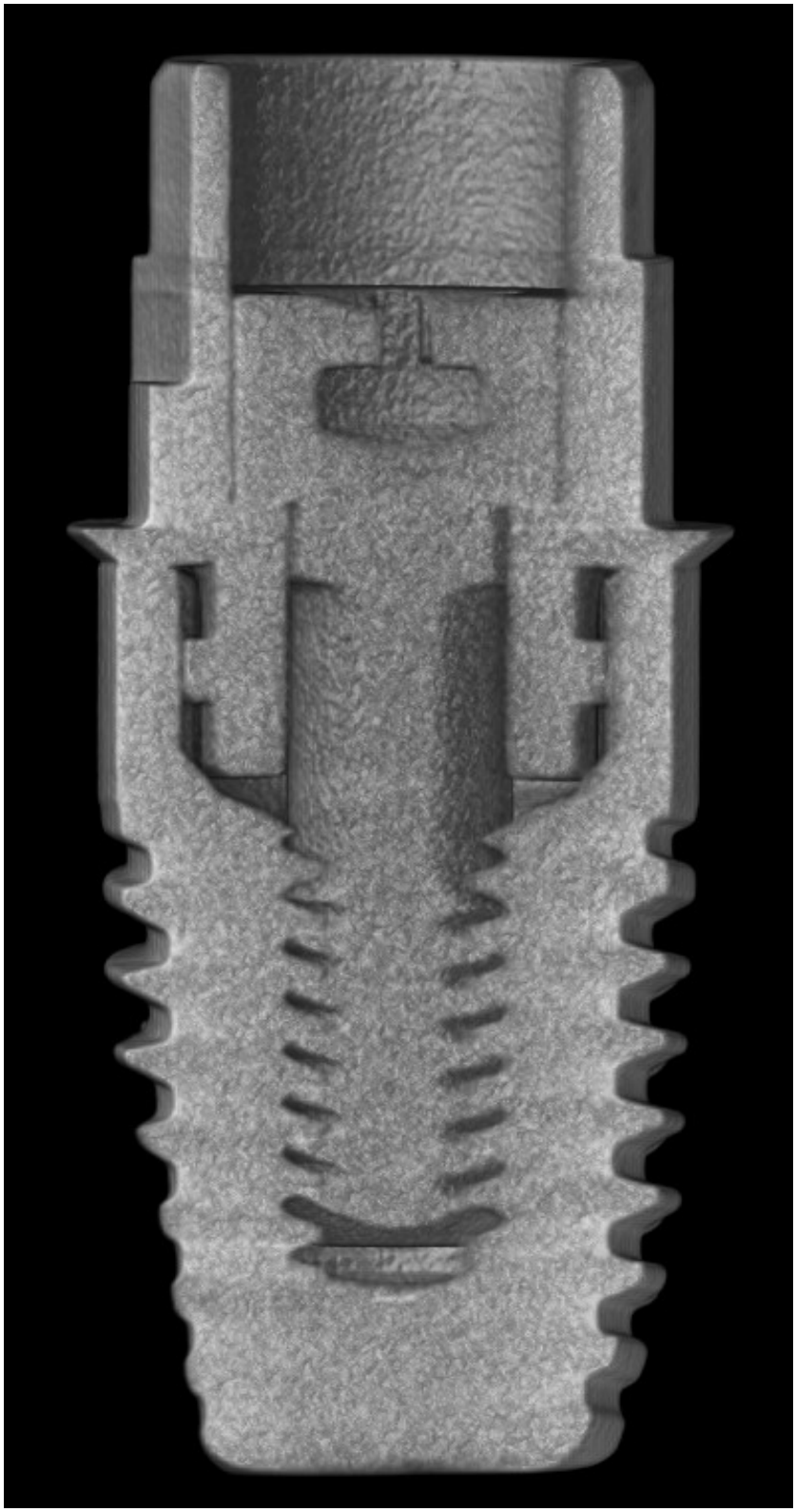


Figure 85: *Specimen 6: Coronal View 1 (anterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

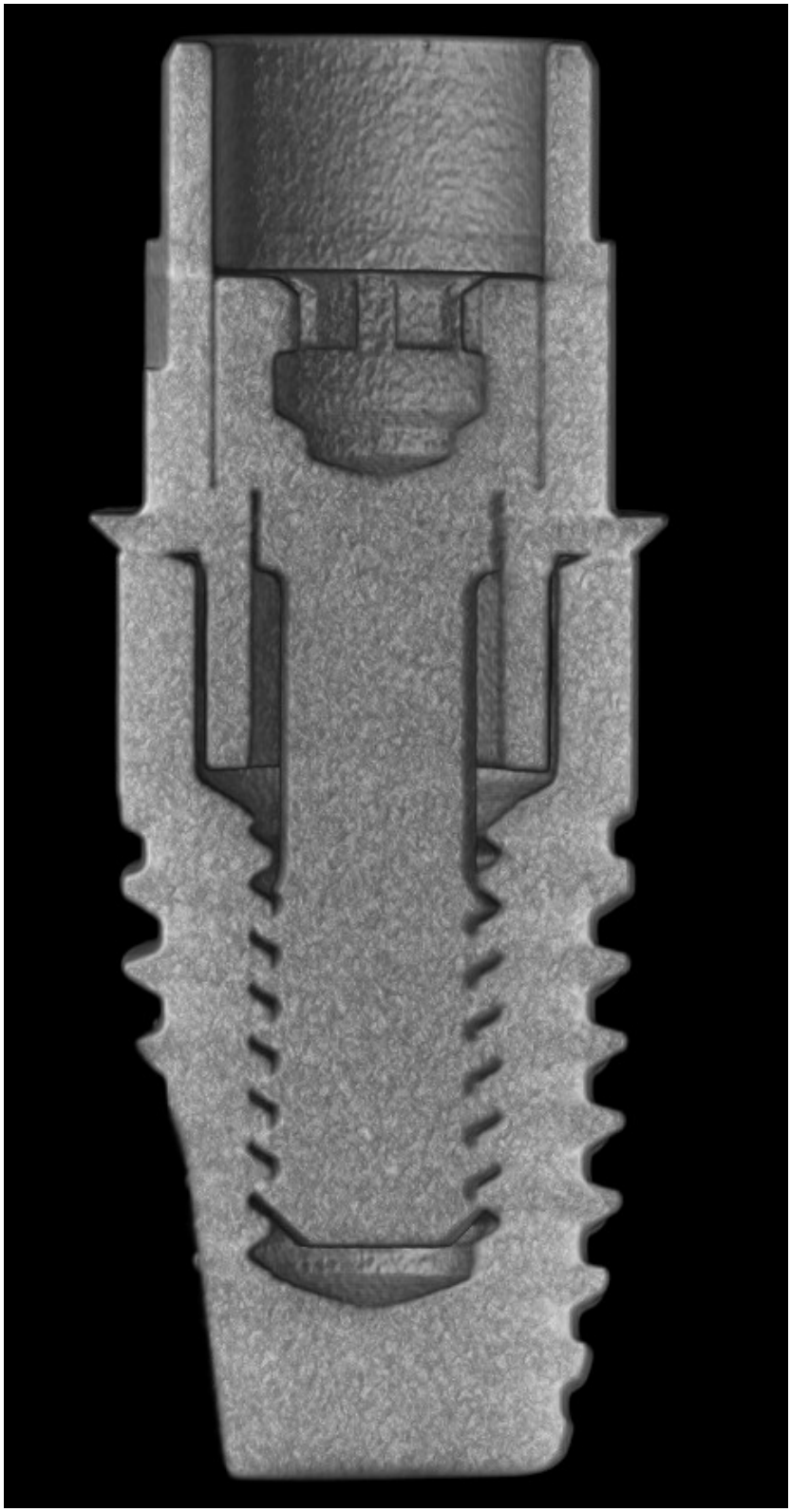


Figure 86: *Specimen 6: Coronal View 1 (midpoint slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

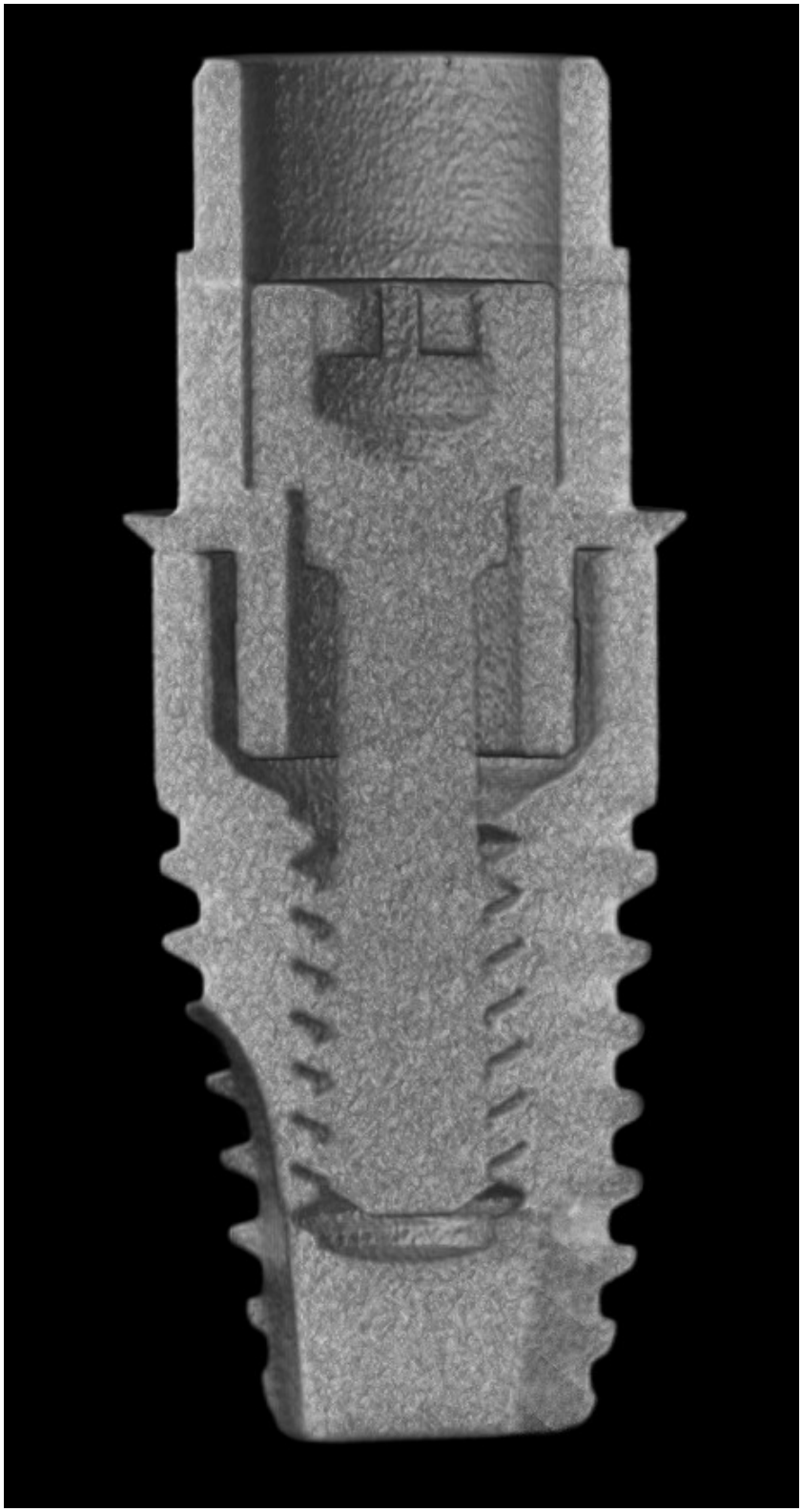


Figure 87: *Specimen 6: Coronal View 1 (posterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

Specimen 7

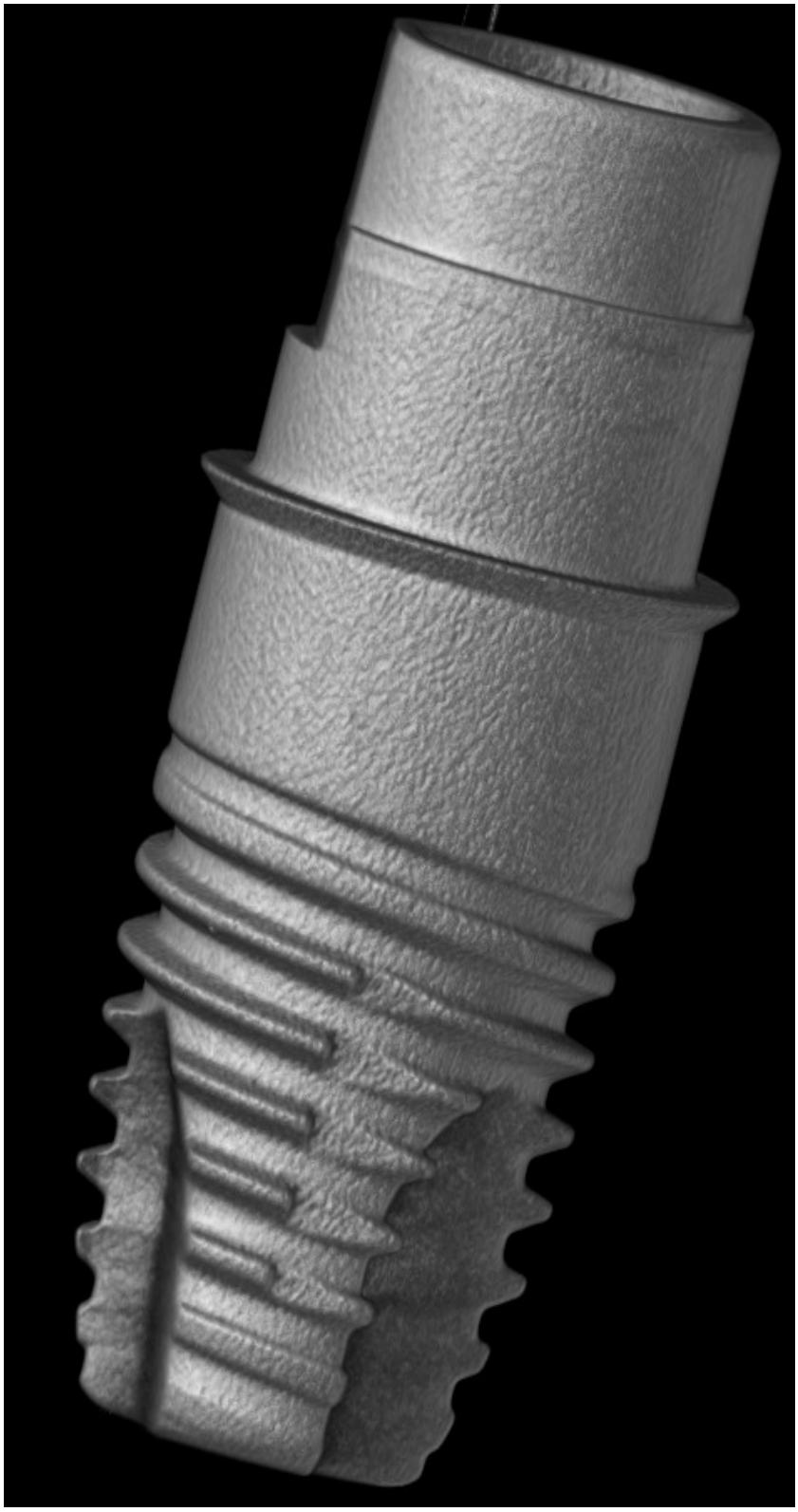


Figure 88: *Specimen 7: External View 1 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

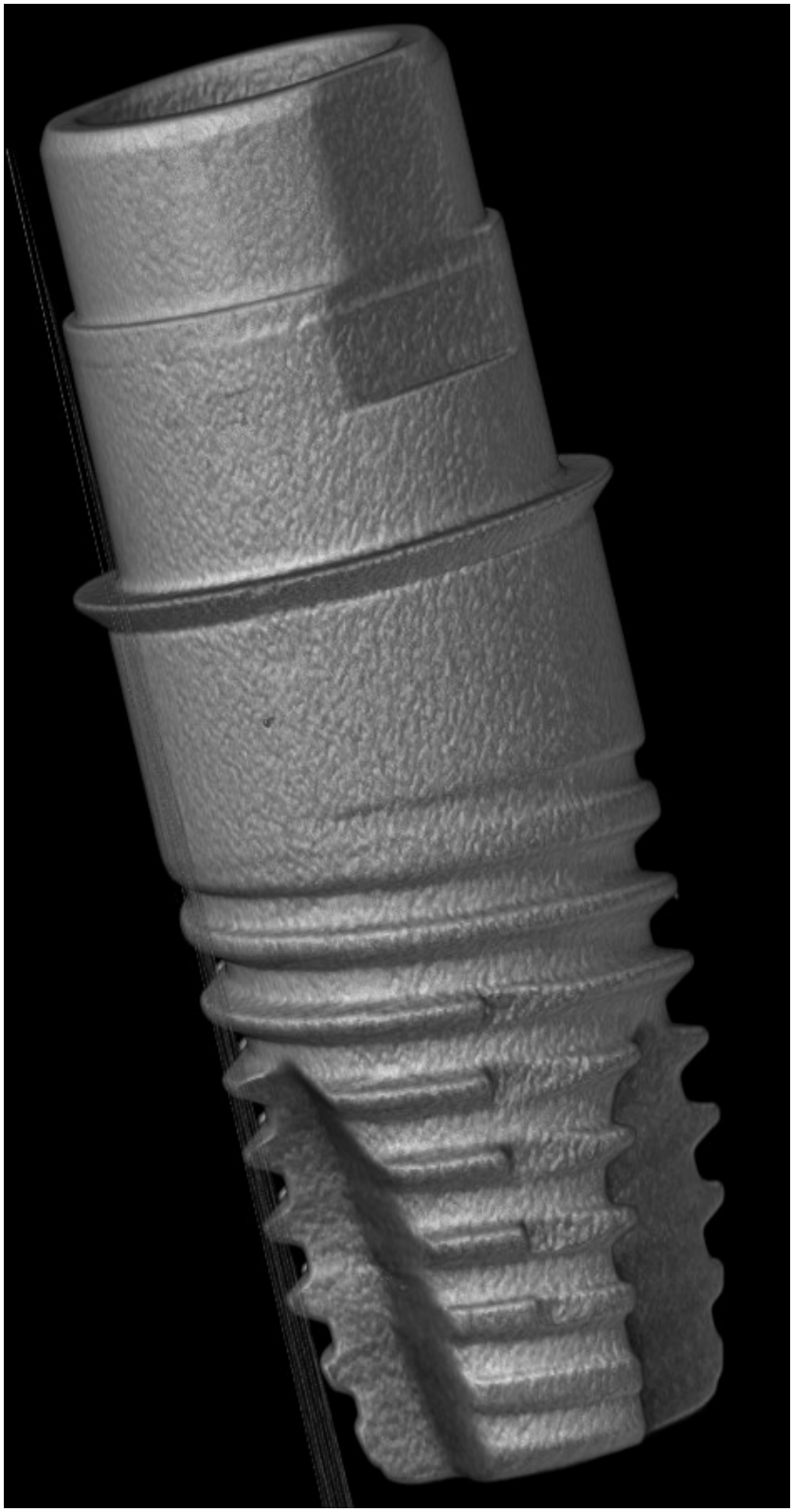


Figure 89: *Specimen 7: External View 2 -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

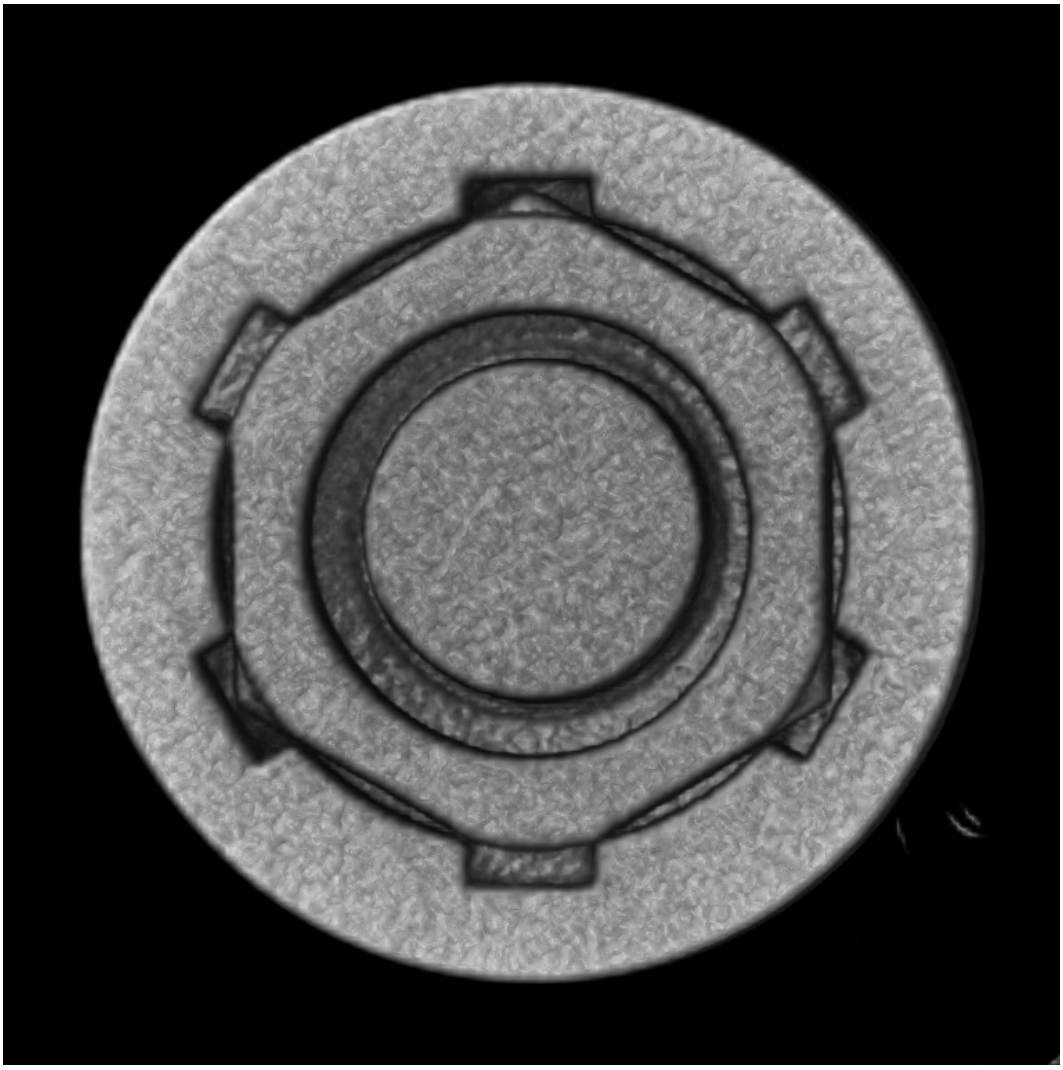


Figure 90: Specimen 7: Cross sectional View 1 (high) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

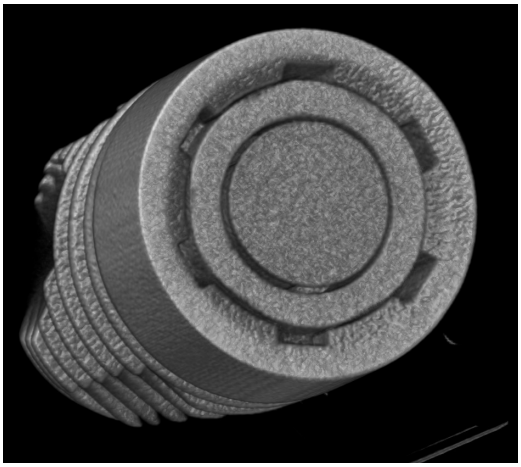


Figure 91: Specimen 7: Cross sectional View 1a (high - adjacent) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

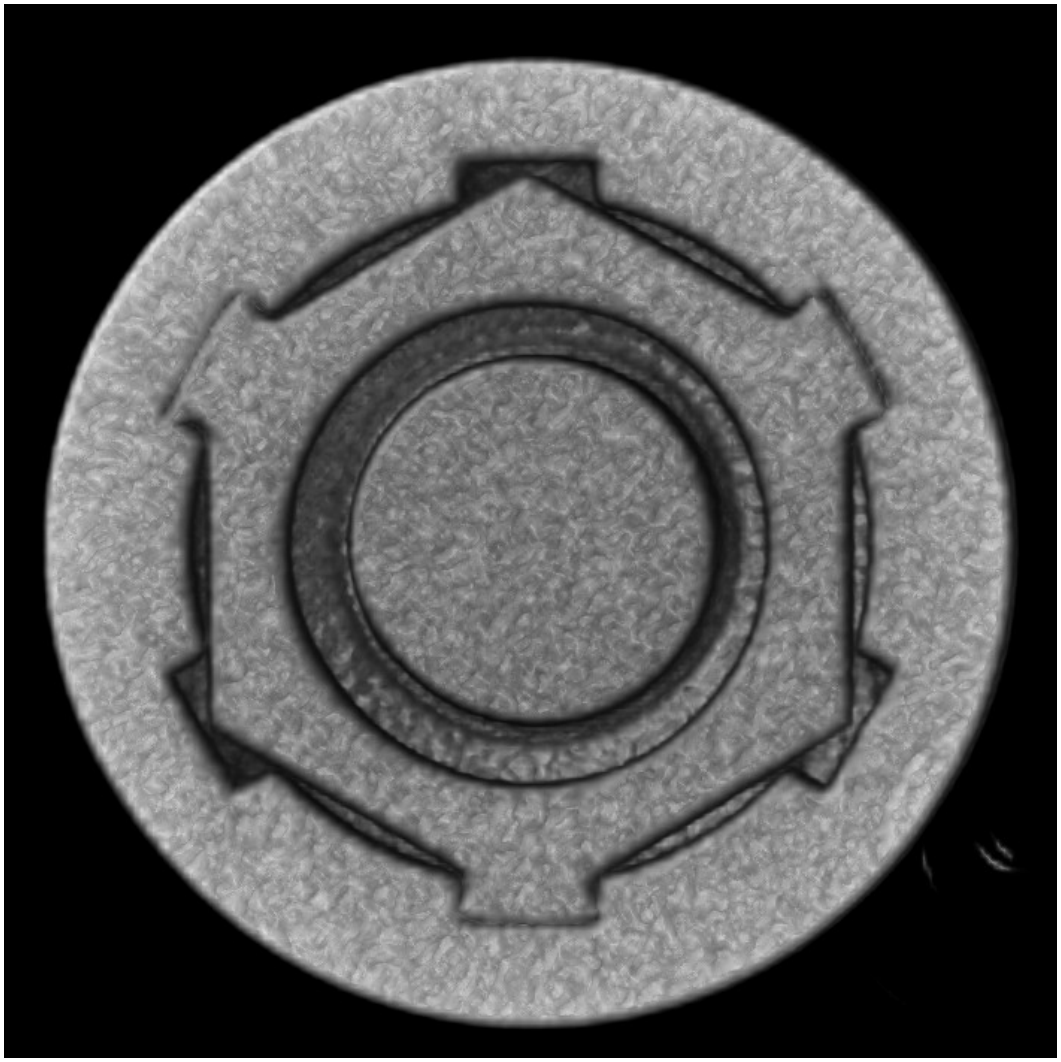


Figure 92: *Specimen 7: Cross sectional View 2 (midpoint slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

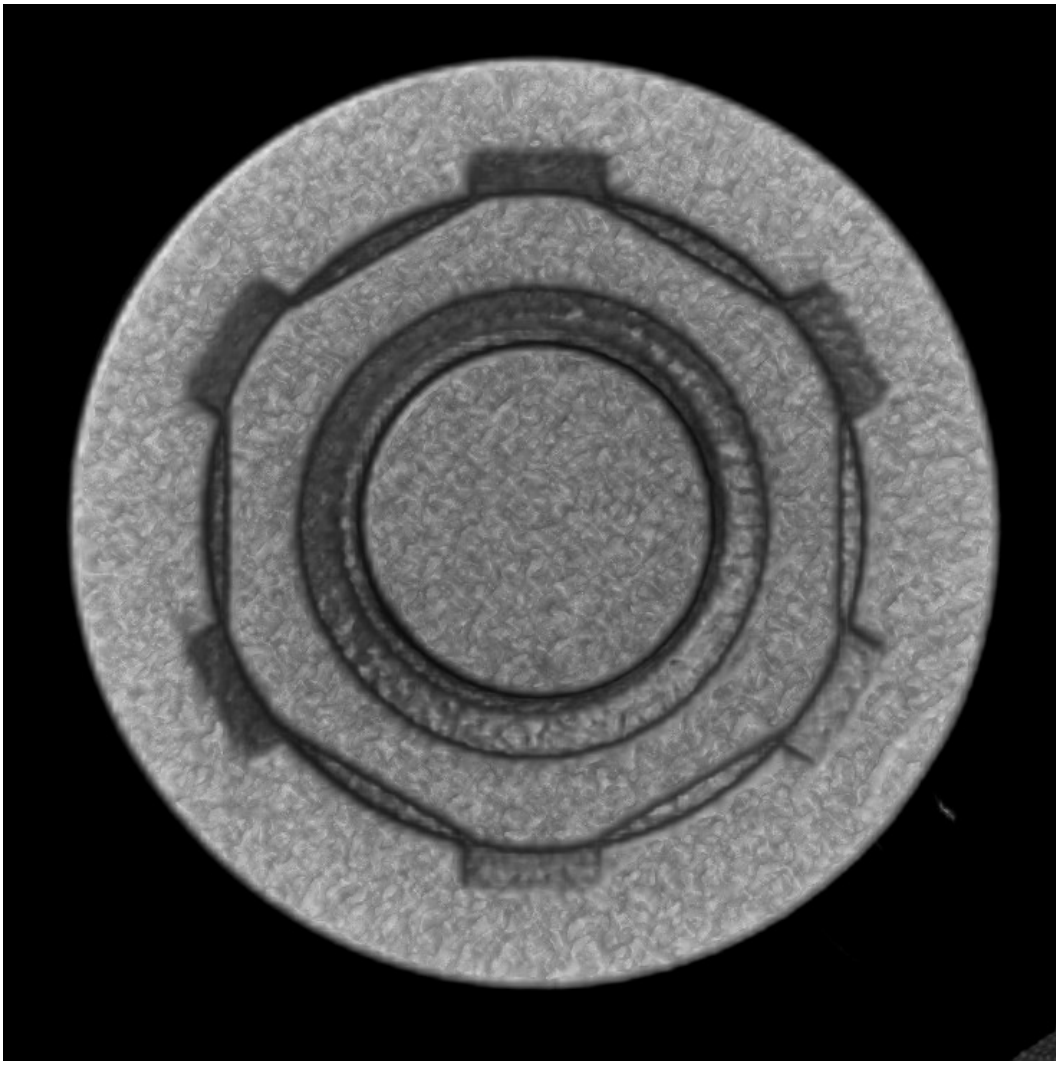


Figure 93: Specimen 7: Cross sectional View 3 (low slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

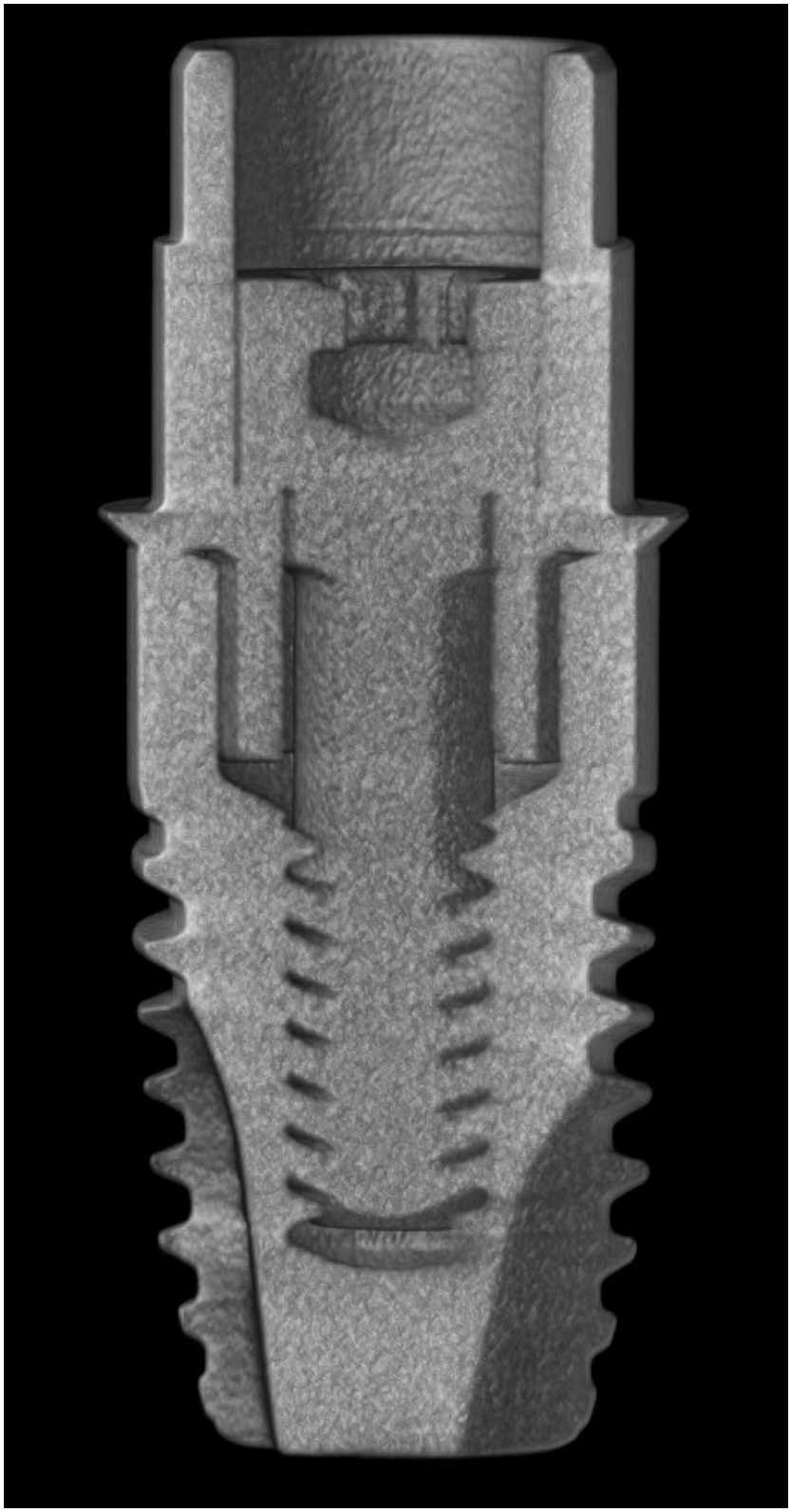


Figure 94: *Specimen 7: Coronal View 1 (anterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

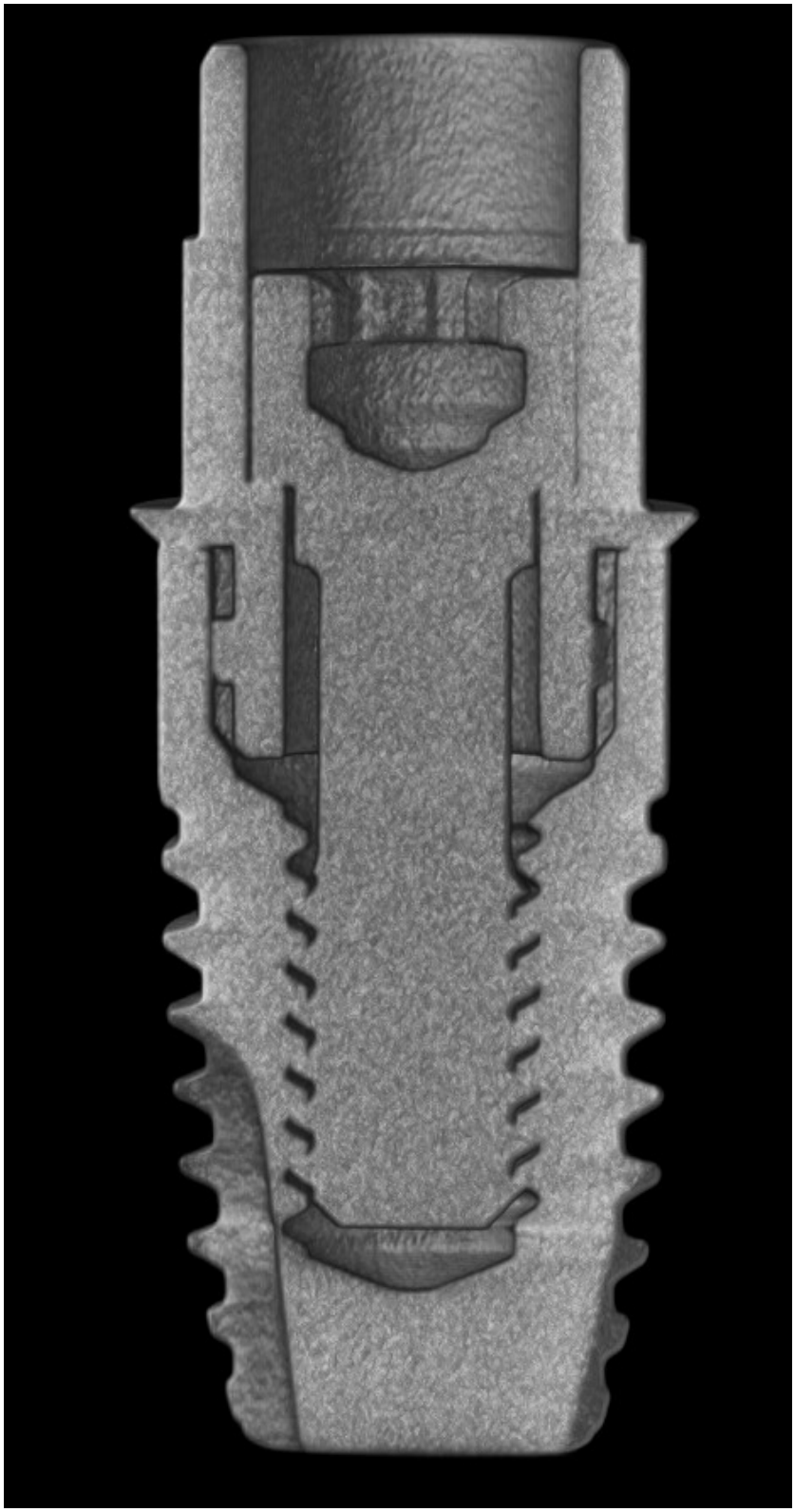


Figure 95: *Specimen 7: Coronal View 2 (midpoint slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant*

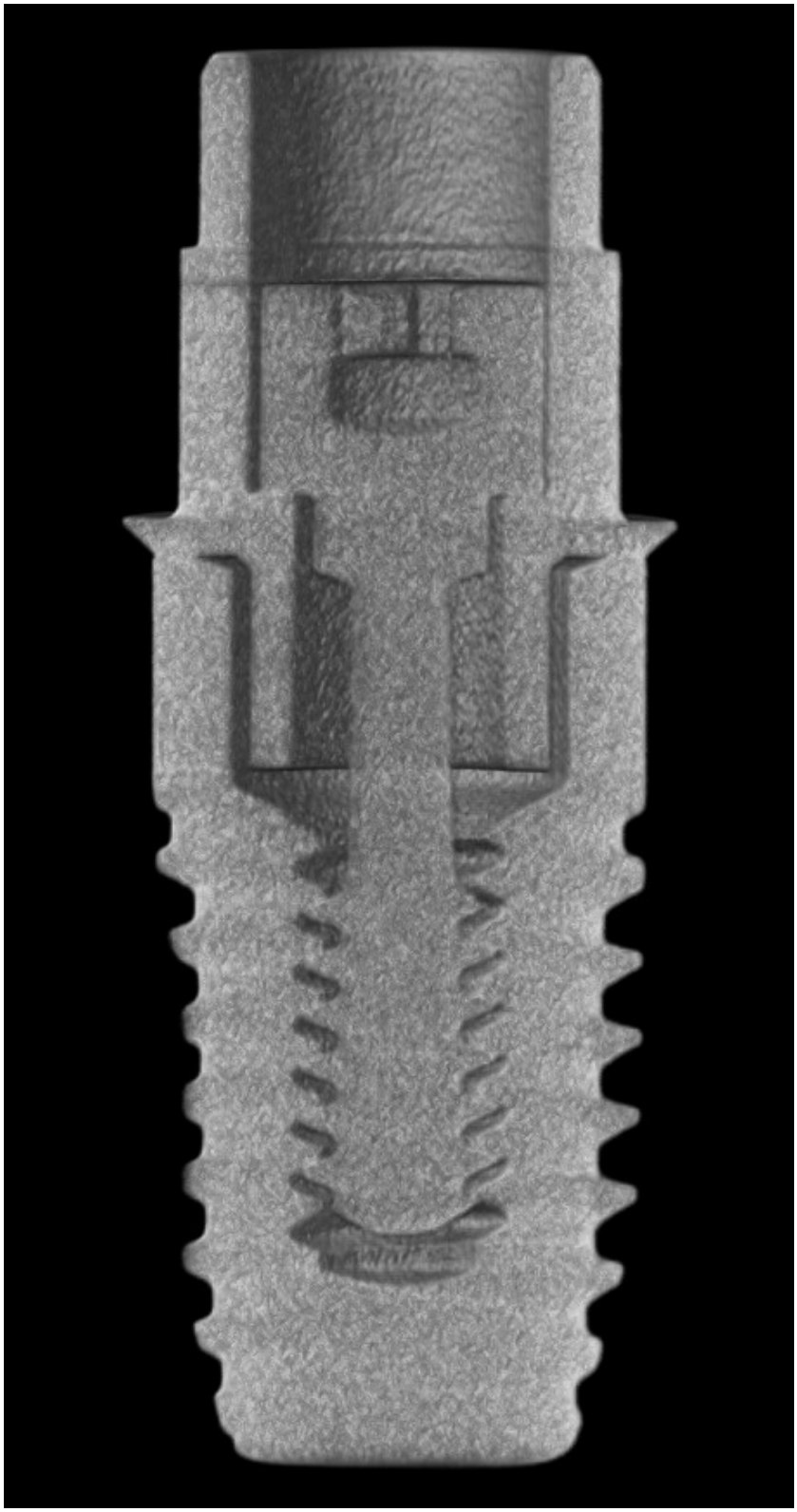


Figure 96: Specimen 7: Coronal View 3 (posterior slice) -- Neoss titanium NeoLink Mono attached to Neoss ProActive implant

Generic group ~ Generic titanium abutments

Specimen 1

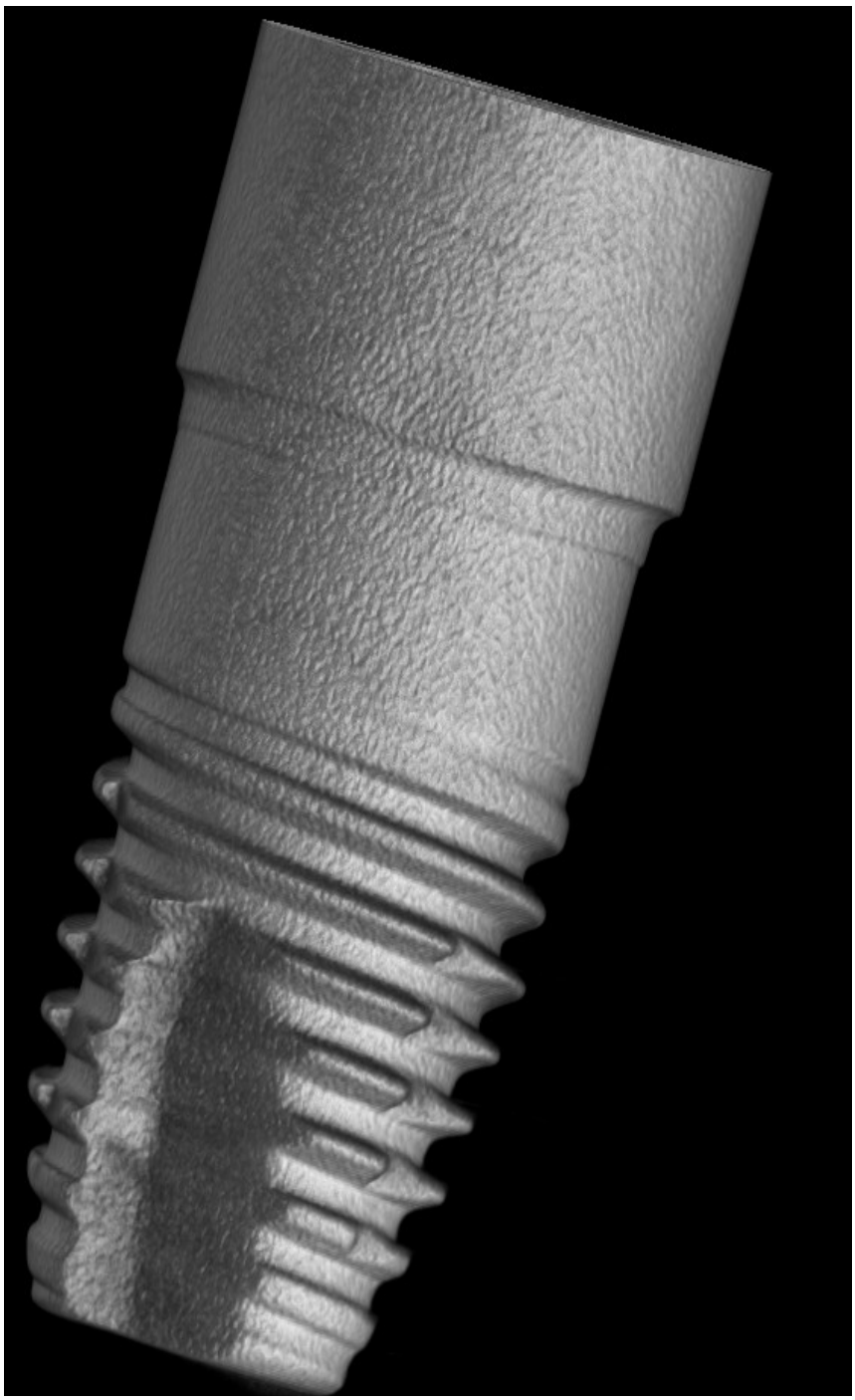


Figure 97: Specimen 1: External View 1 – Generic titanium abutment attached to Neoss ProActive implant

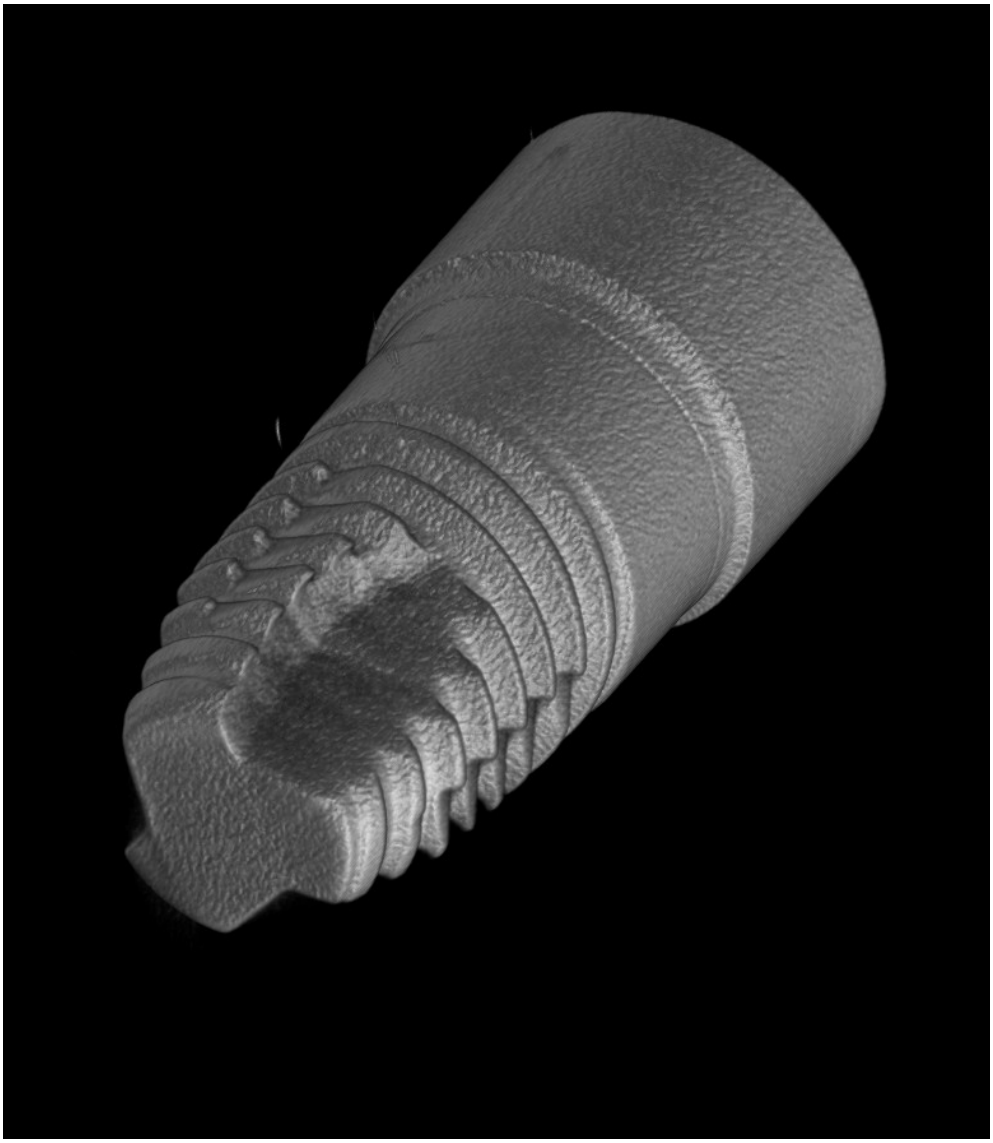


Figure 98: *Specimen 1: External View 1 – Generic titanium abutment attached to Neoss ProActive implant*

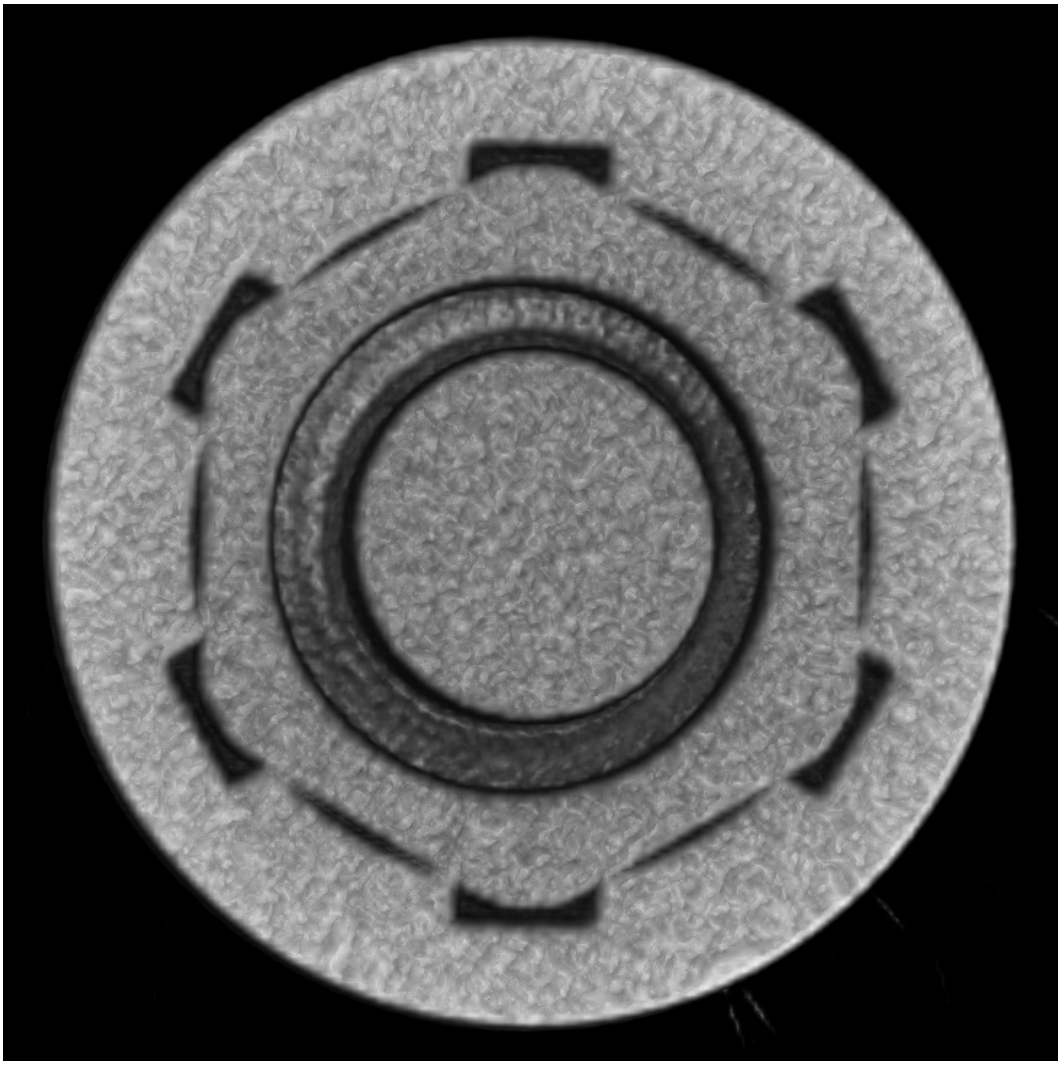


Figure 99: Specimen 1: Cross sectional View 1 (high) -- Generic titanium abutment attached to Neoss ProActive implant

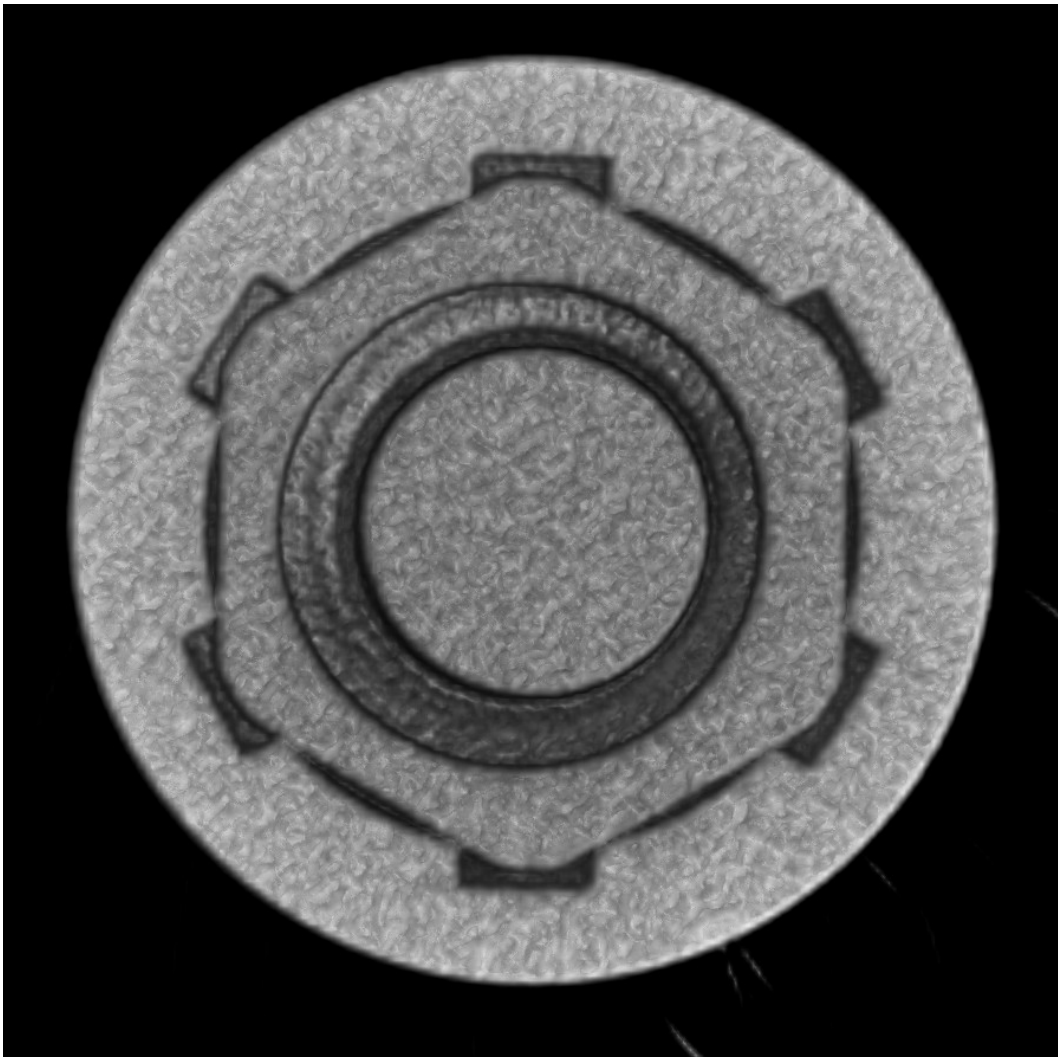


Figure 100: Specimen 1: Cross sectional View 2 (low) -- Generic titanium abutment attached to Neoss ProActive implant

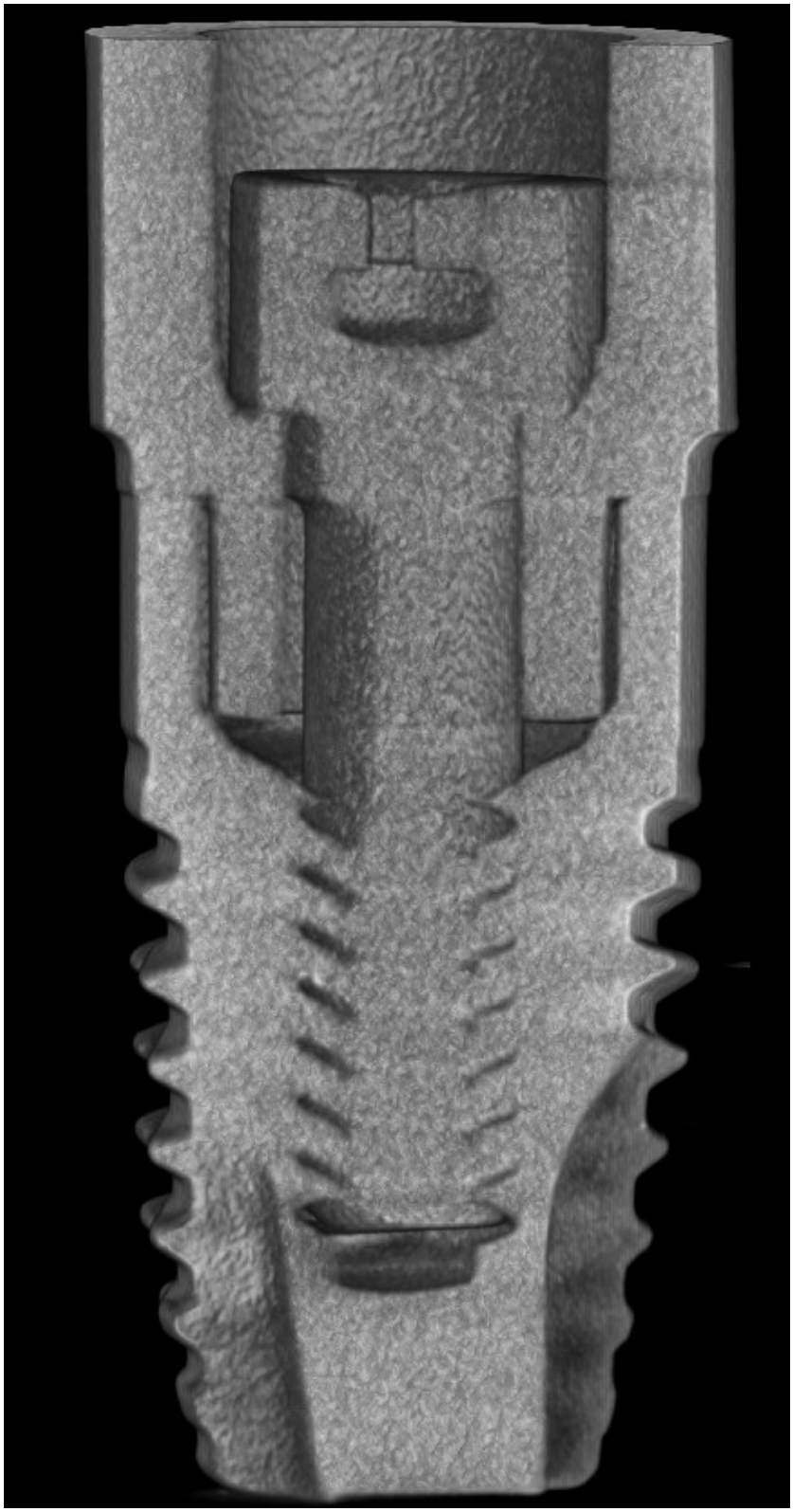


Figure 101: *Specimen 1: Coronal View 1 (anterior slice) -- Generic titanium abutment attached to Neoss ProActive implant*

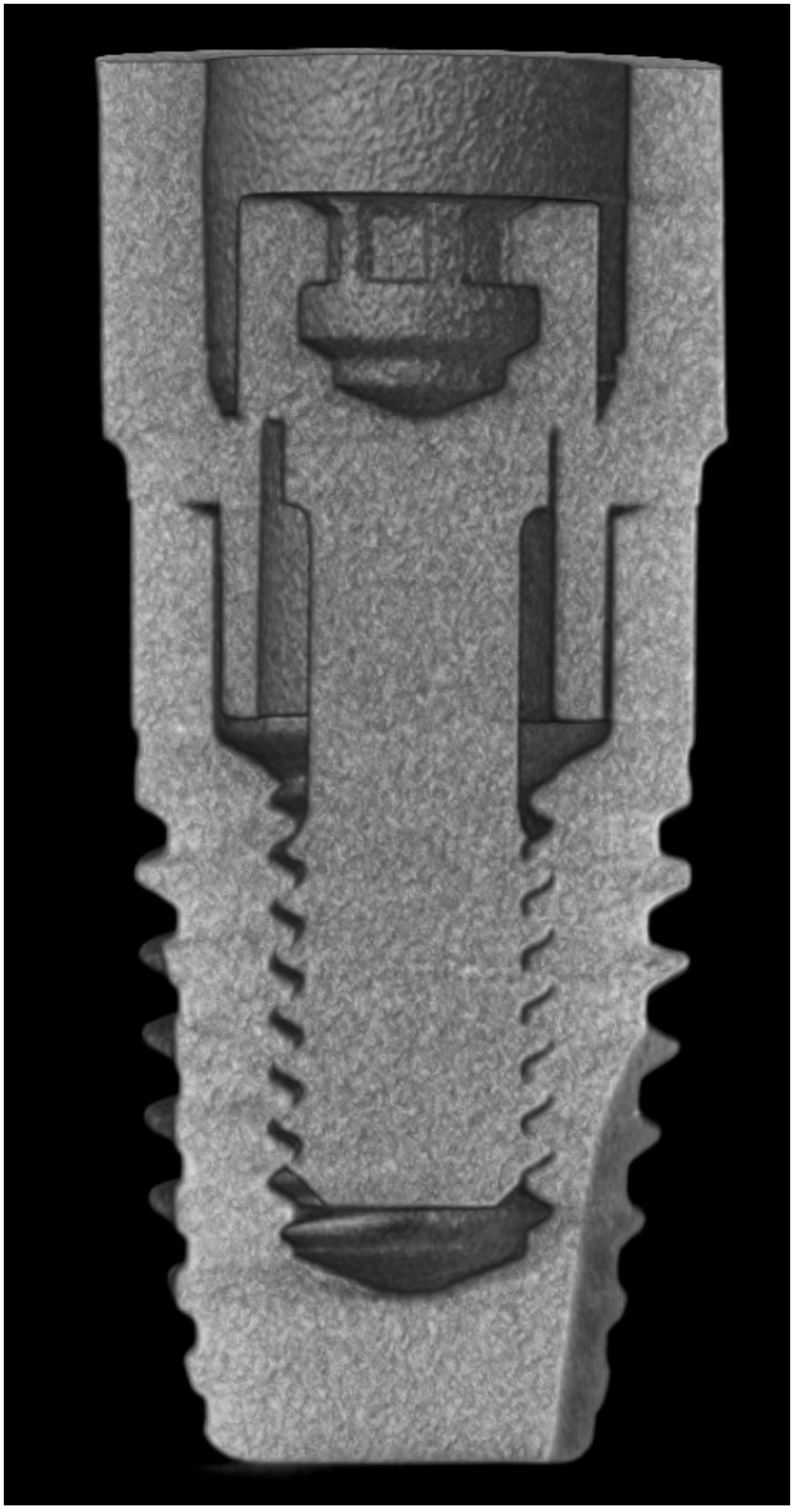


Figure 102: Specimen 1: Coronal View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

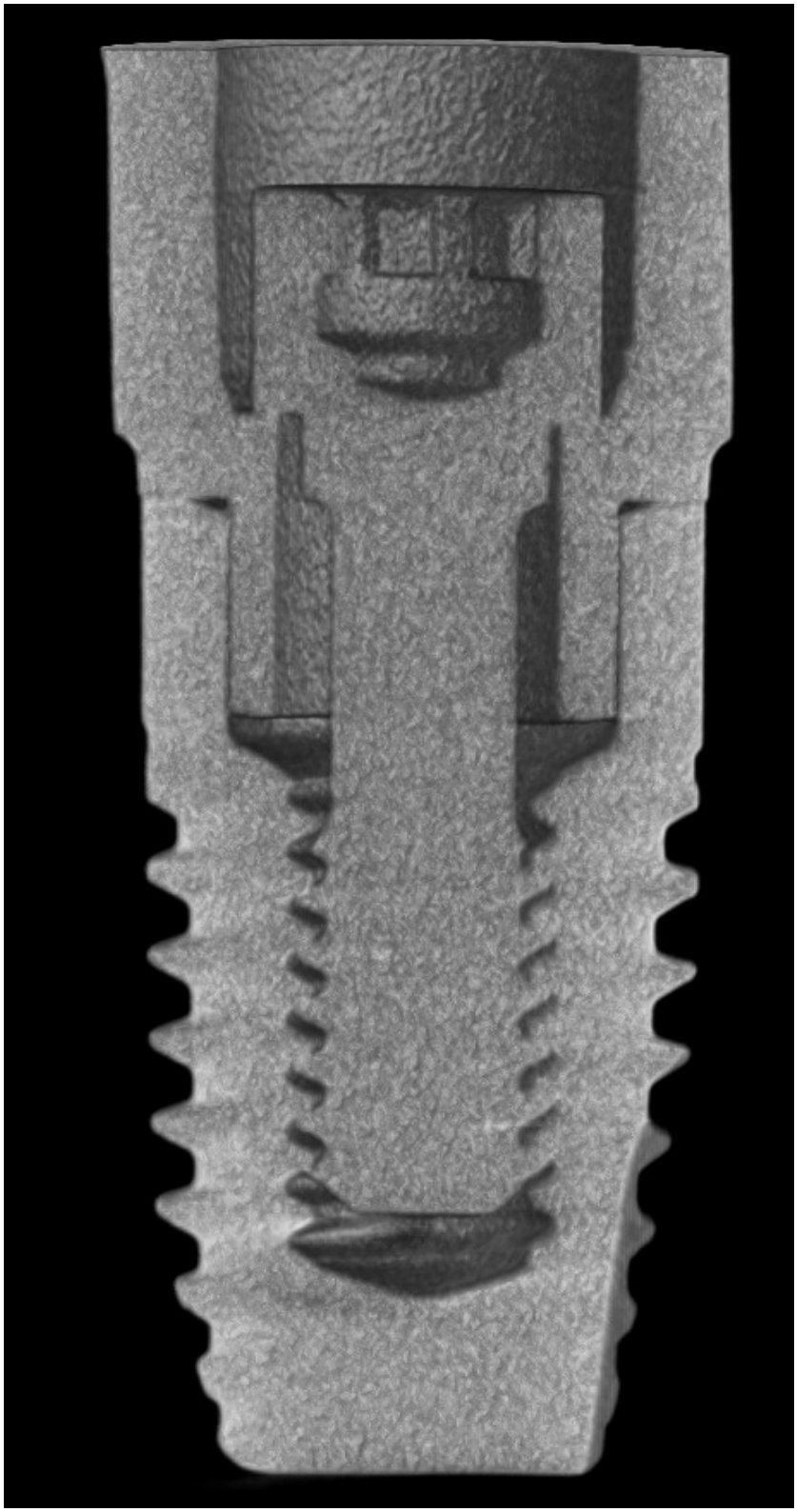


Figure 103: *Specimen 1: Coronal View 3 (posterior slice) -- Generic titanium abutment attached to Neoss ProActive implant*

Specimen 2

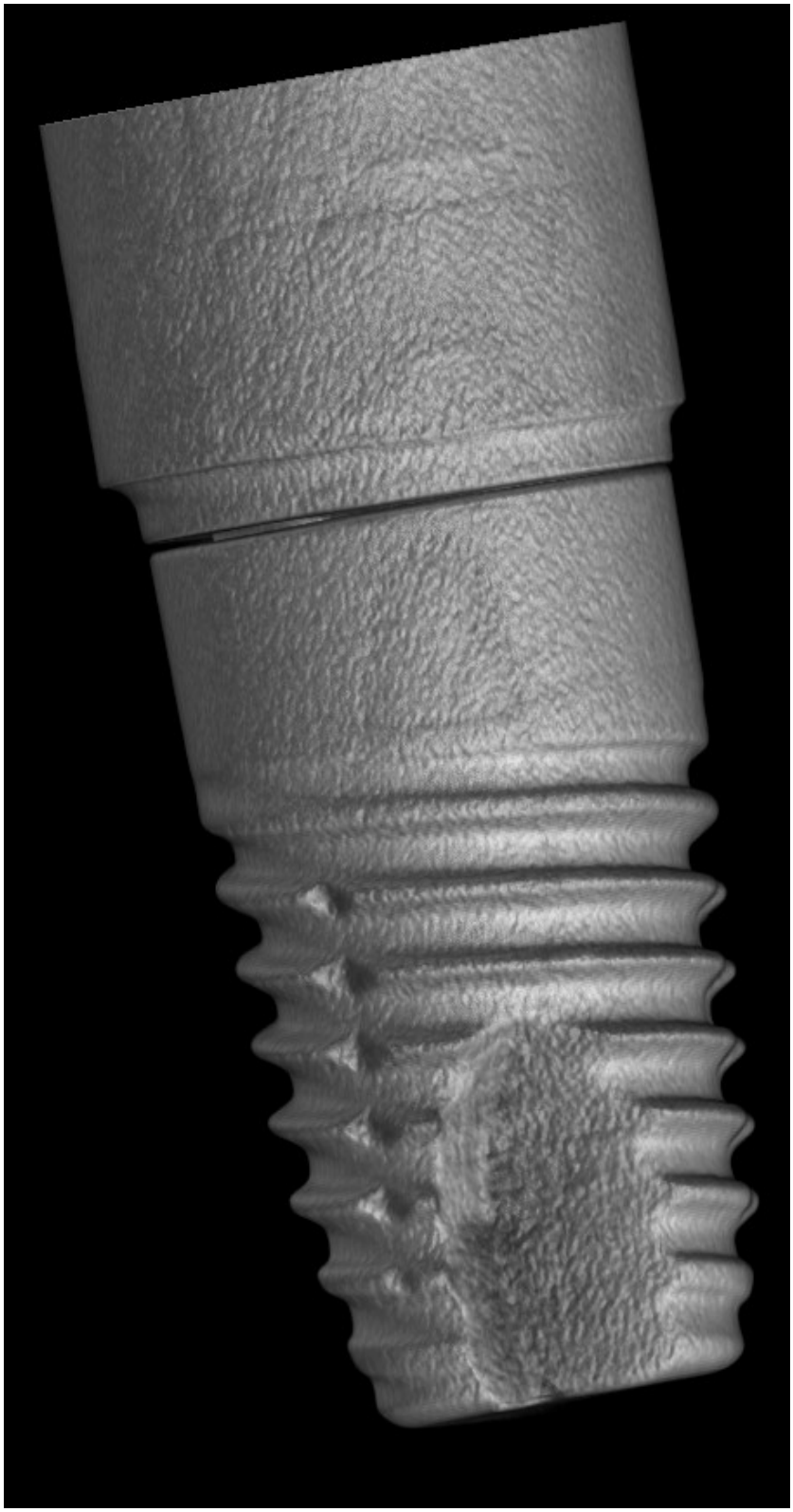


Figure 104: Specimen 2: External View 1 – Generic titanium abutment attached to Neoss ProActive implant

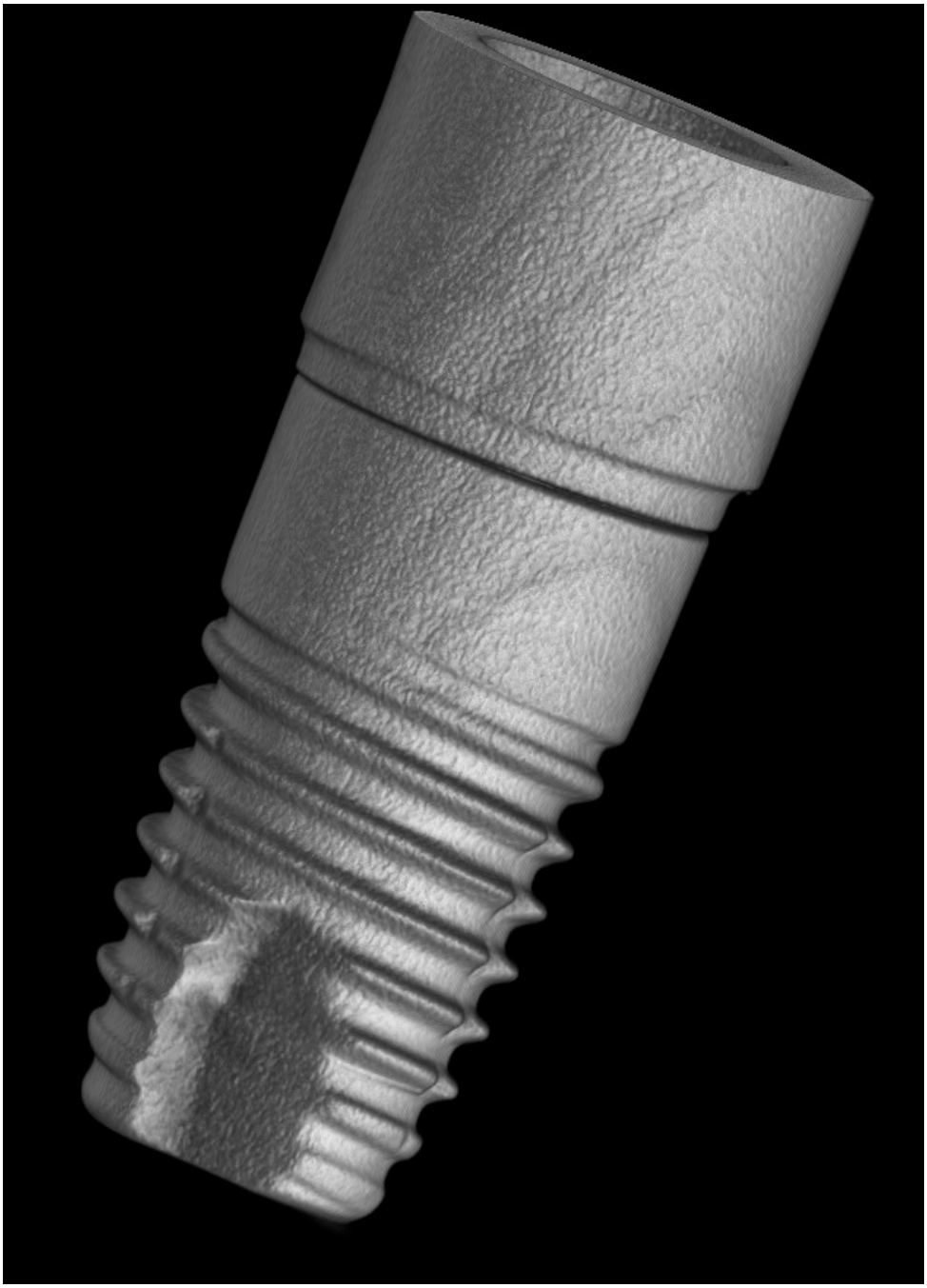


Figure 105: Specimen 2: External View 2 – Generic titanium abutment attached to Neoss ProActive implant

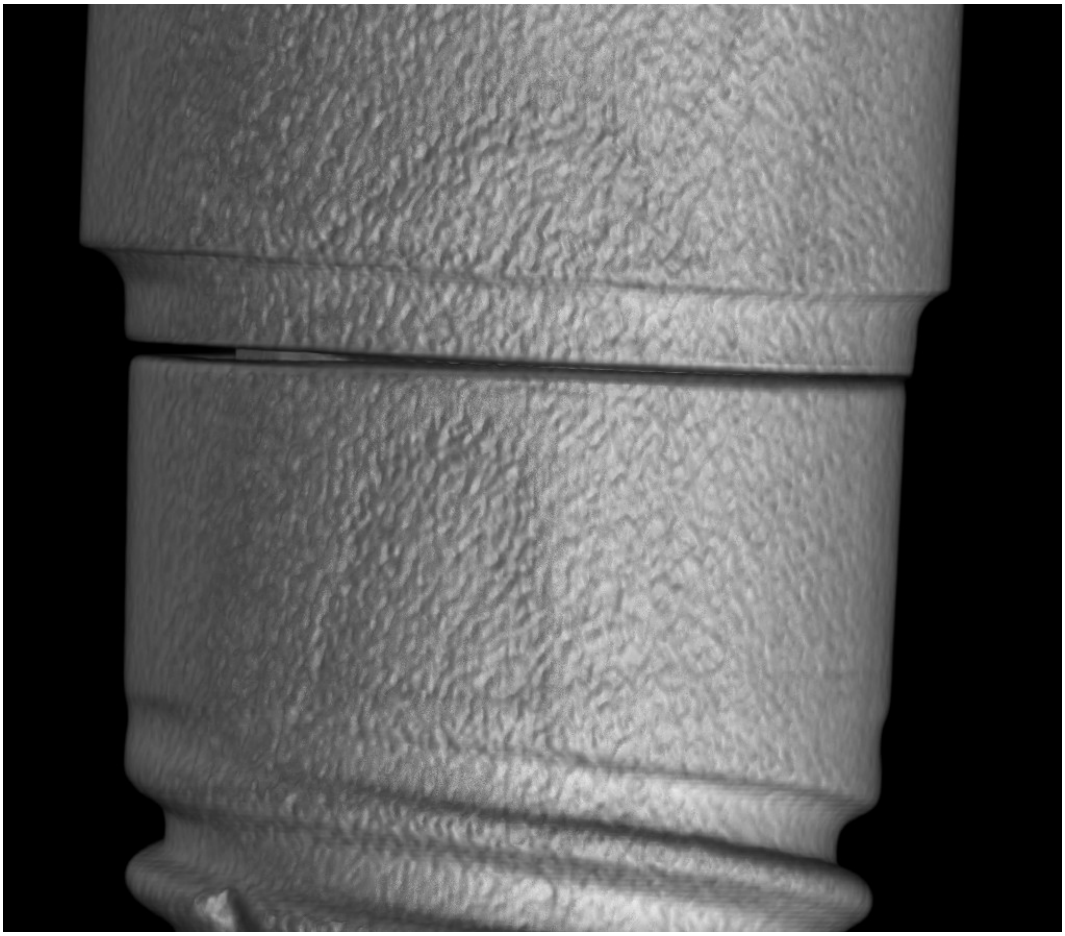


Figure 106: Specimen 2: External View 3 (zoom)– Generic titanium abutment attached to Neoss ProActive implant

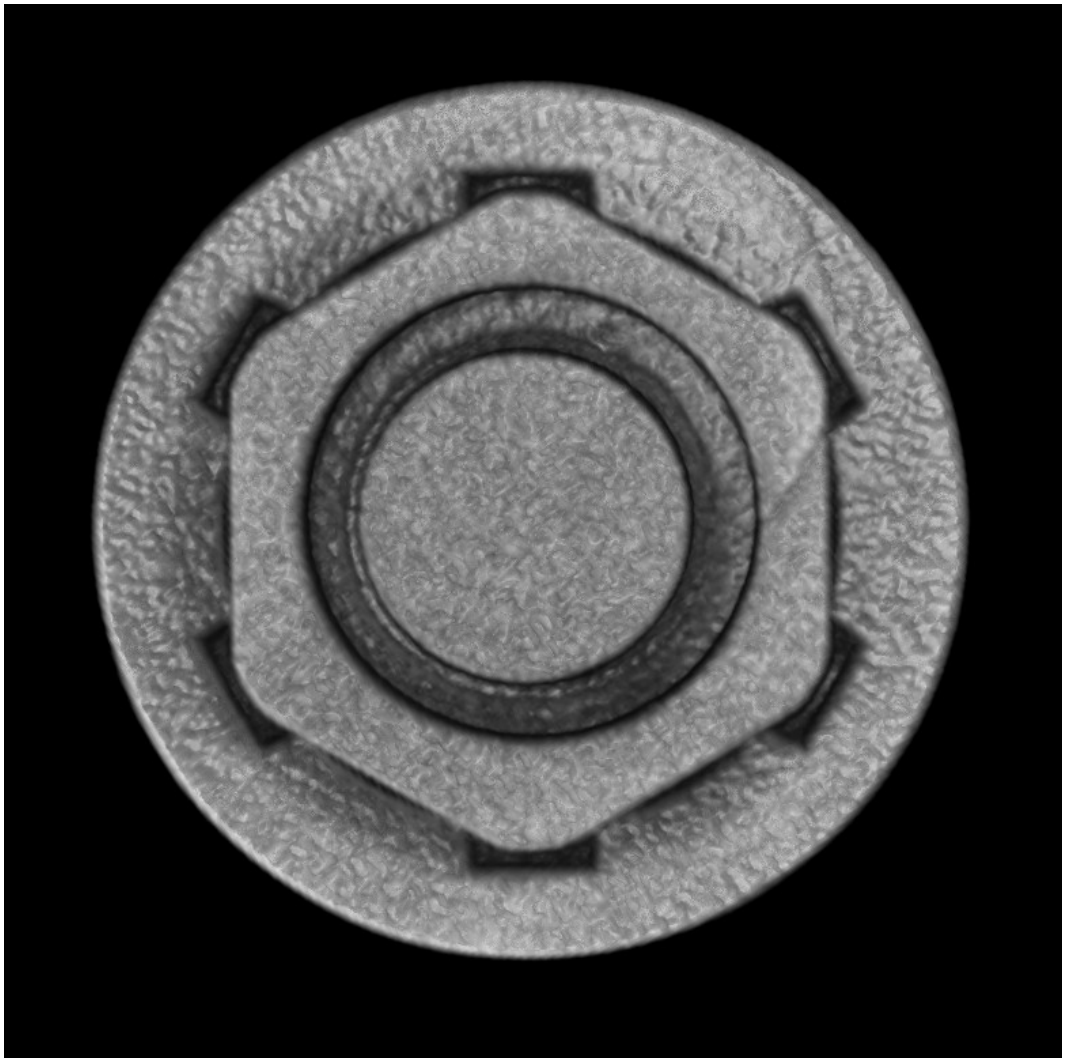


Figure 107: Specimen 2: Cross sectional View 1 (high) -- Generic titanium abutment attached to Neoss ProActive implant

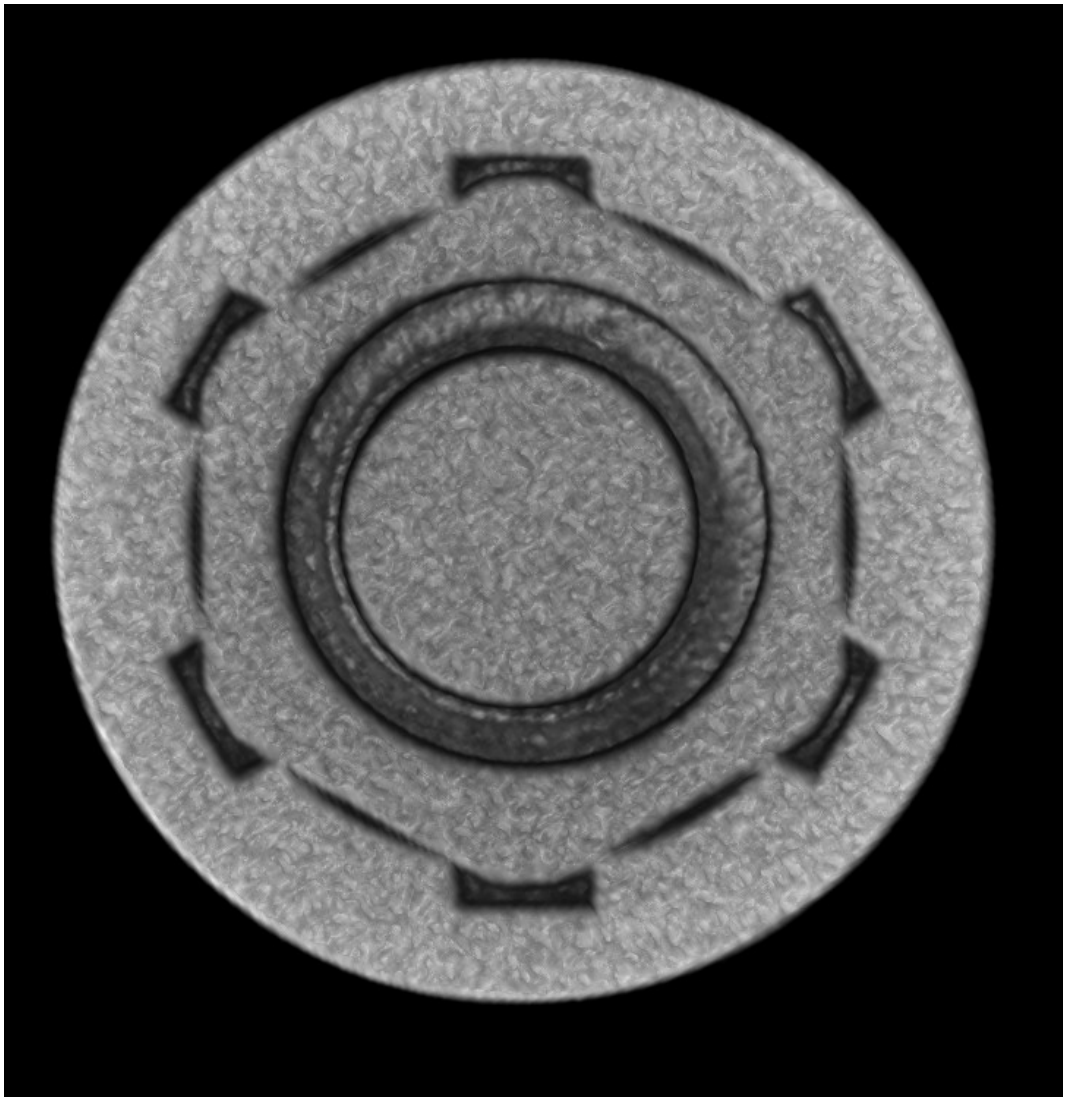


Figure 108: *Specimen 2: Cross sectional View 2 (midpoint) -- Generic titanium abutment attached to Neoss ProActive implant*

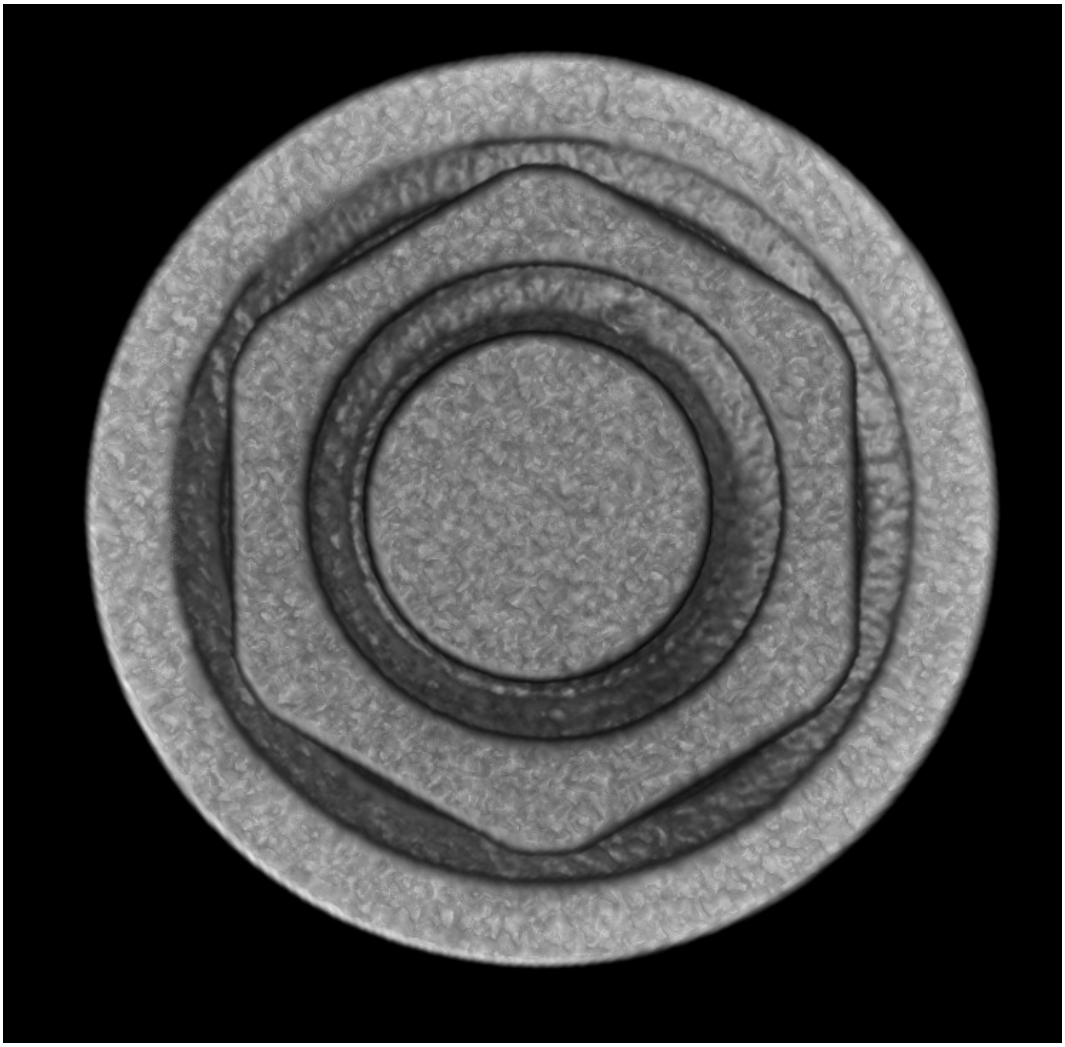


Figure 109: *Specimen 2: Cross sectional View 3 (low slice) -- Generic titanium abutment attached to Neoss ProActive implant*

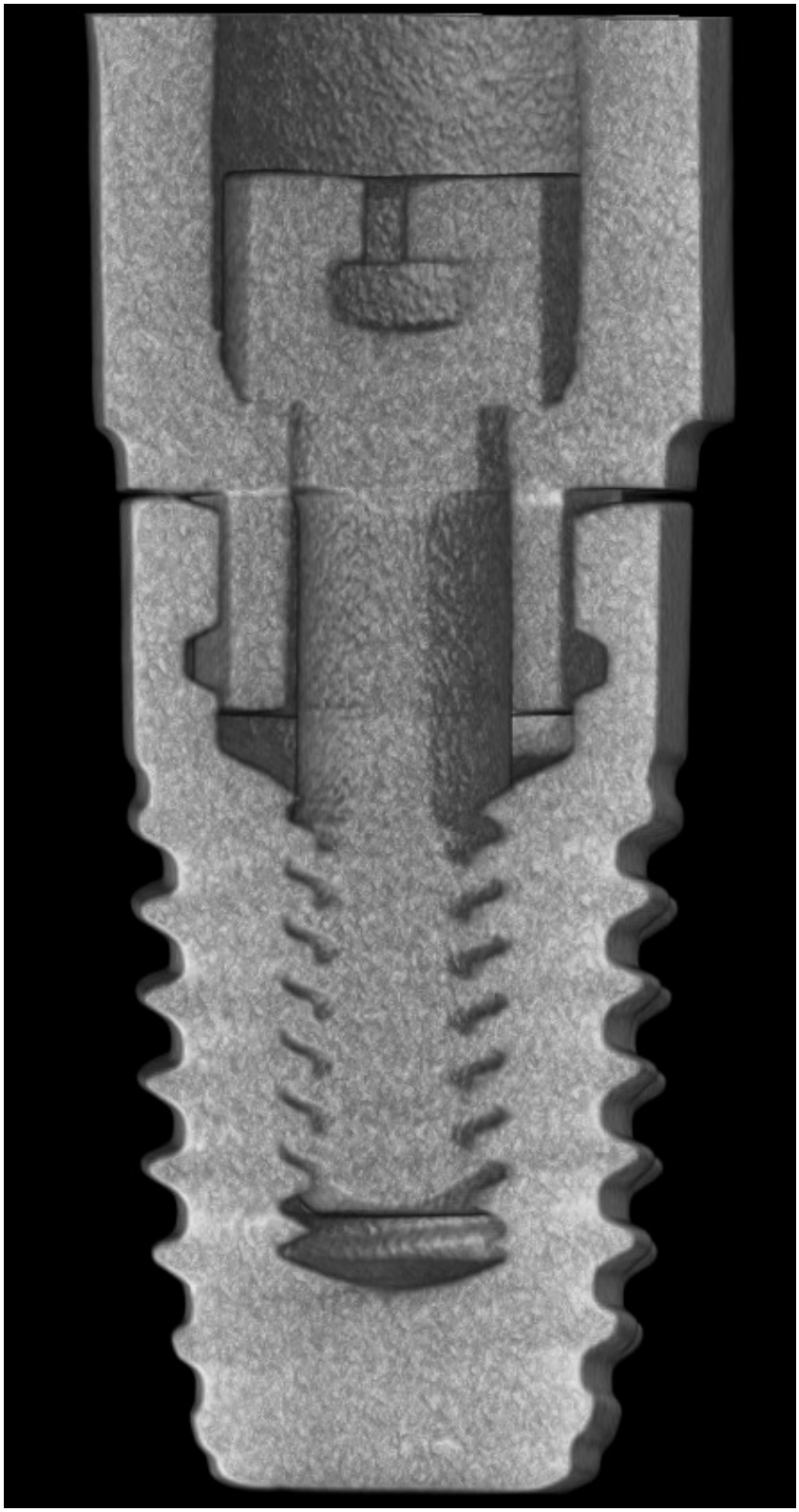


Figure 110: Specimen 2: Coronal View 1 (anterior slice) -- Generic titanium abutment attached to Neoss ProActive implant

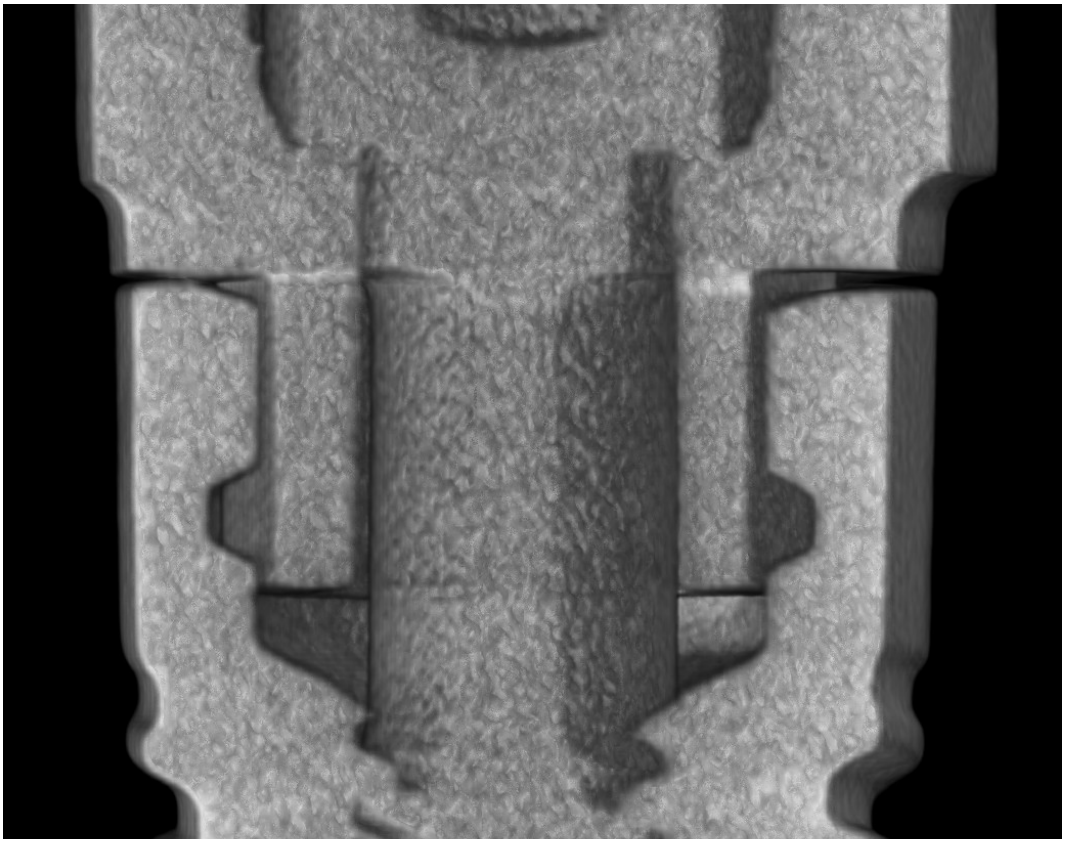


Figure 111: Specimen 2: Coronal View 1a (anterior slice zoom) -- Generic titanium abutment attached to Neoss ProActive implant

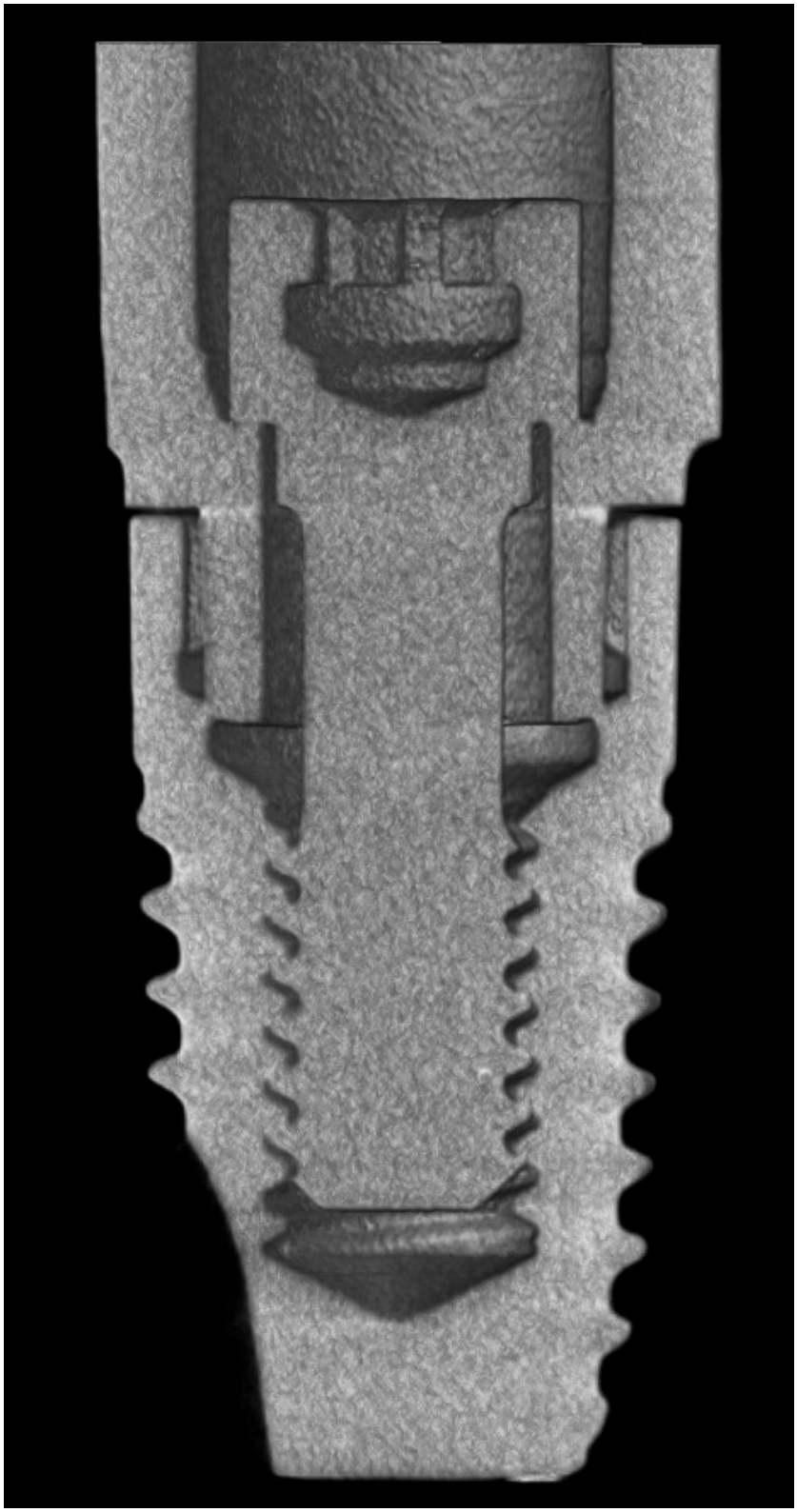


Figure 112: Specimen 2: Coronal View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

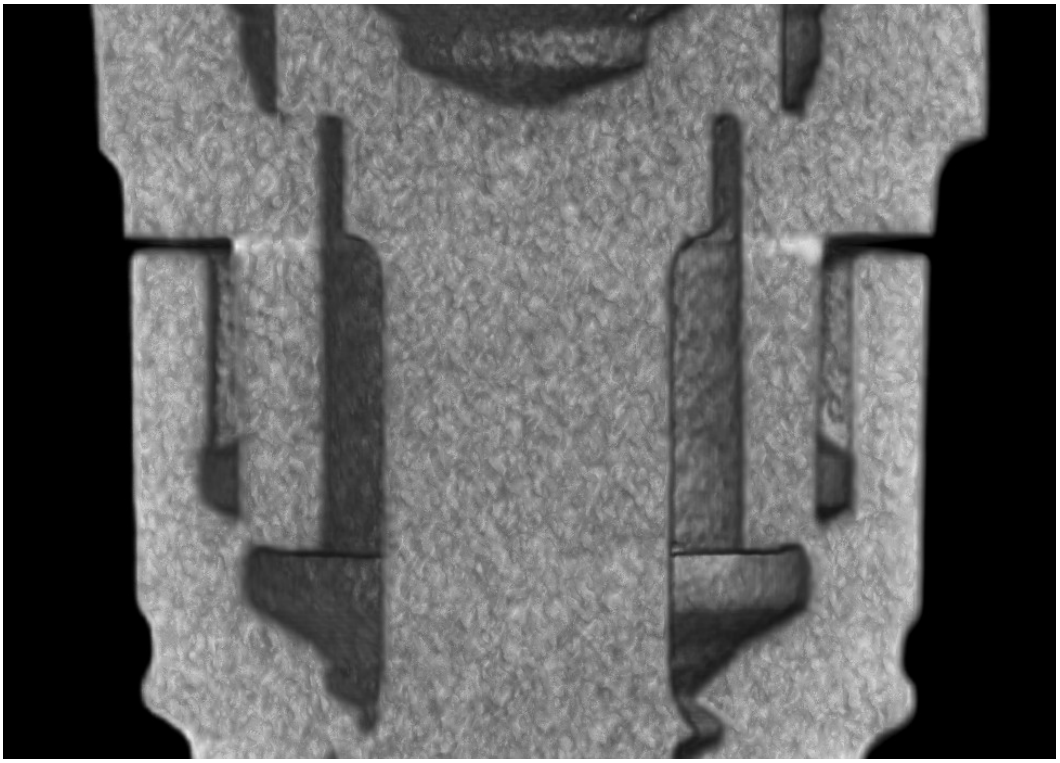


Figure 113: Specimen 2: Coronal View 2a (midpoint slice zoom) -- Generic titanium abutment attached to Neoss ProActive implant

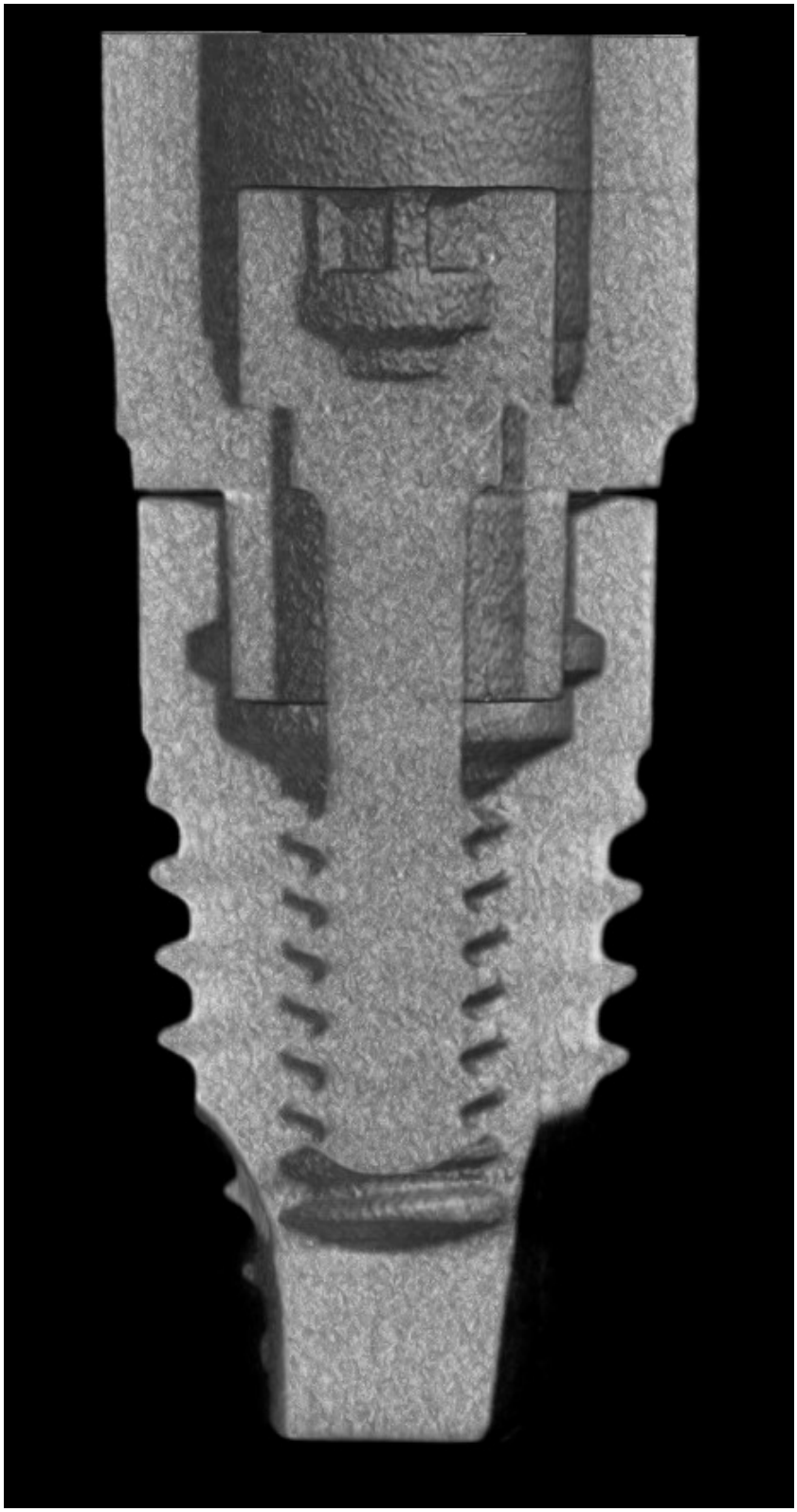


Figure 114: *Specimen 2: Coronal View 3 (posterior slice) -- Generic titanium abutment attached to Neoss ProActive implant*

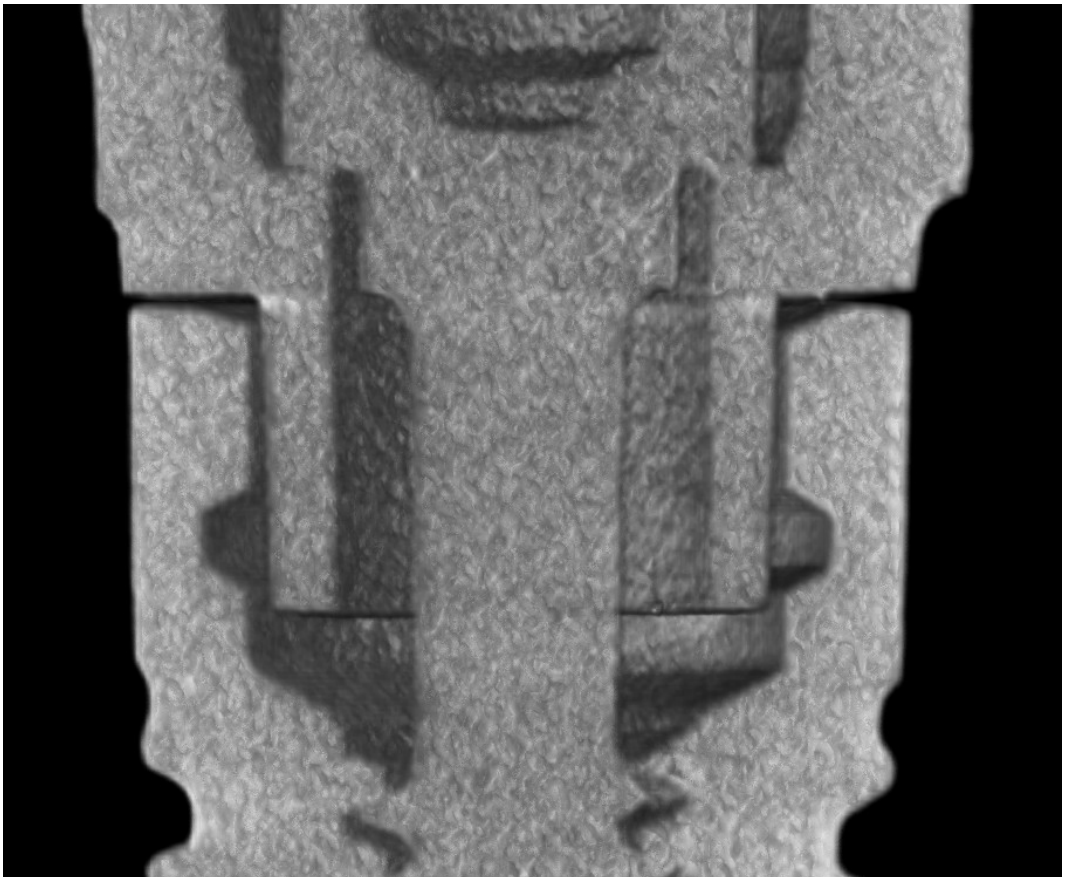


Figure 115: Specimen 2: Coronal View 3a (posterior slice zoom) -- Generic titanium abutment attached to Neoss ProActive implant

Specimen 3

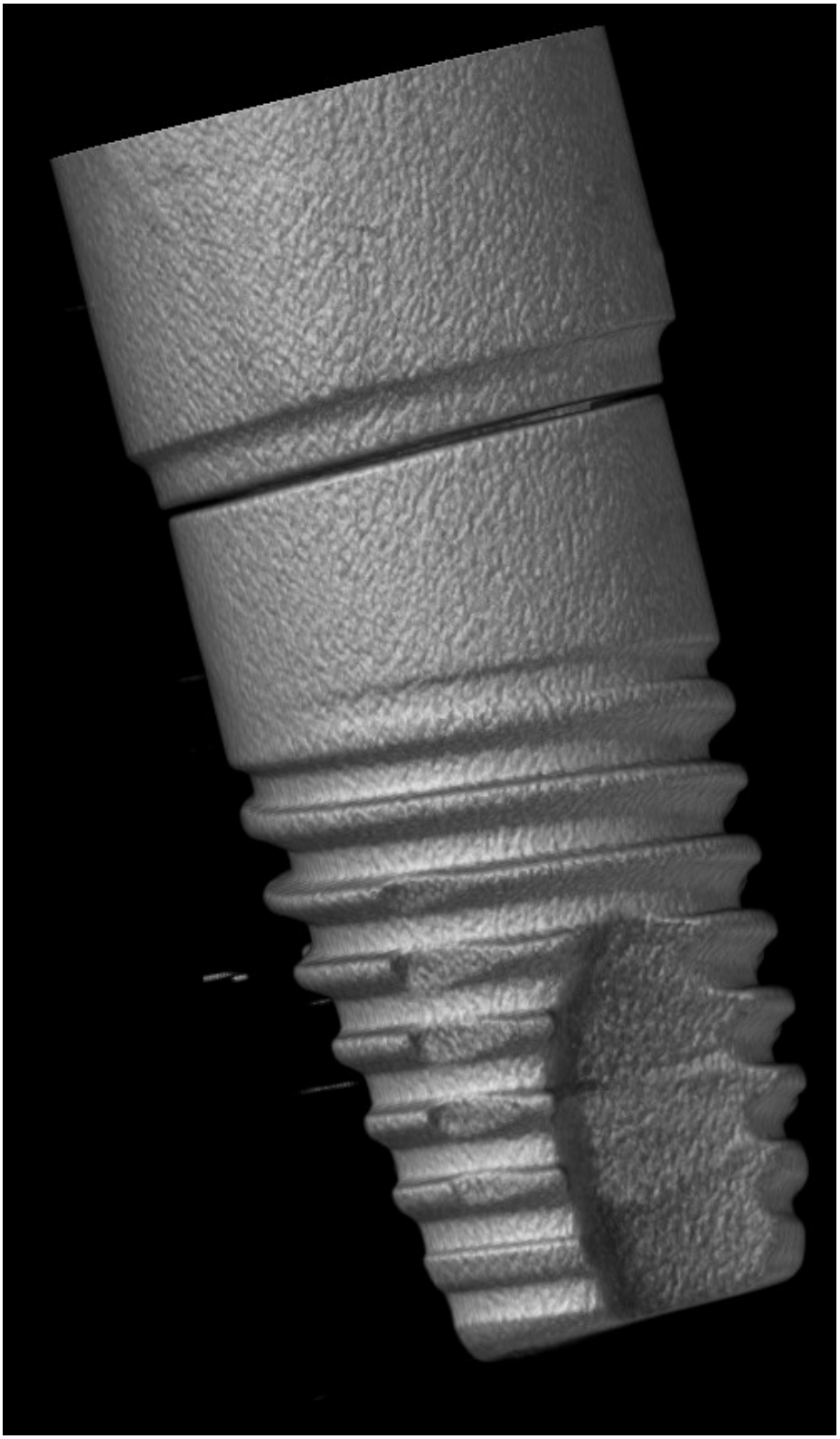


Figure 116: Specimen 3: External View 1 – Generic titanium abutment attached to Neoss ProActive implant

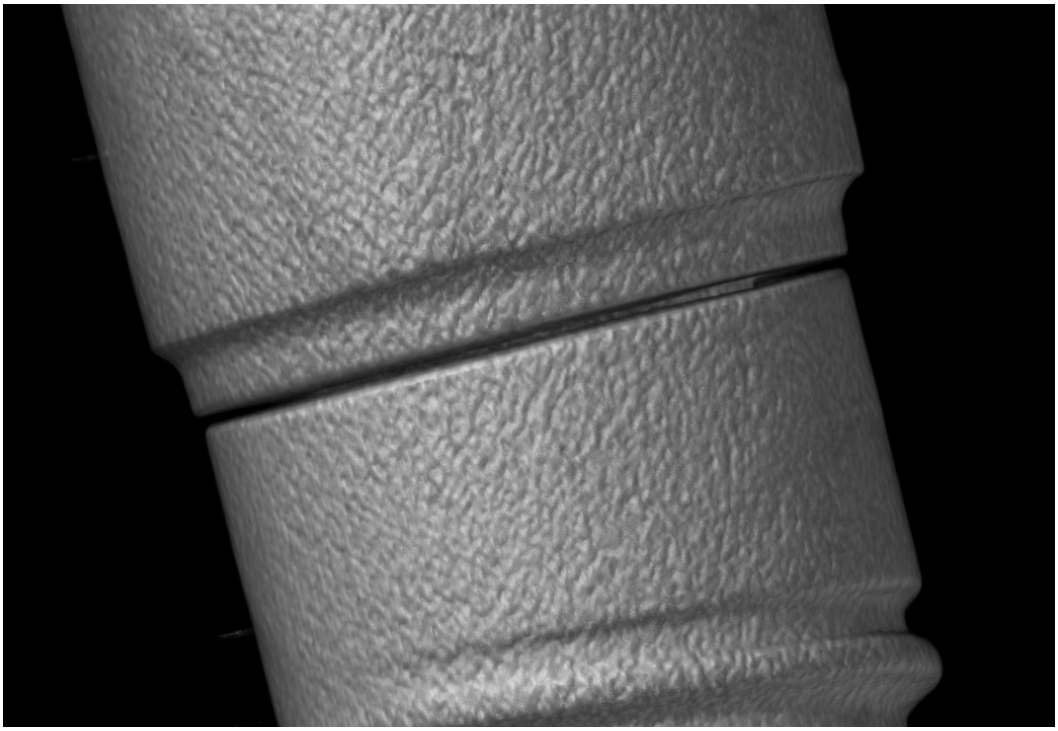


Figure 117: Specimen 3: External View 1a (zoom) – Generic titanium abutment attached to Neoss ProActive implant

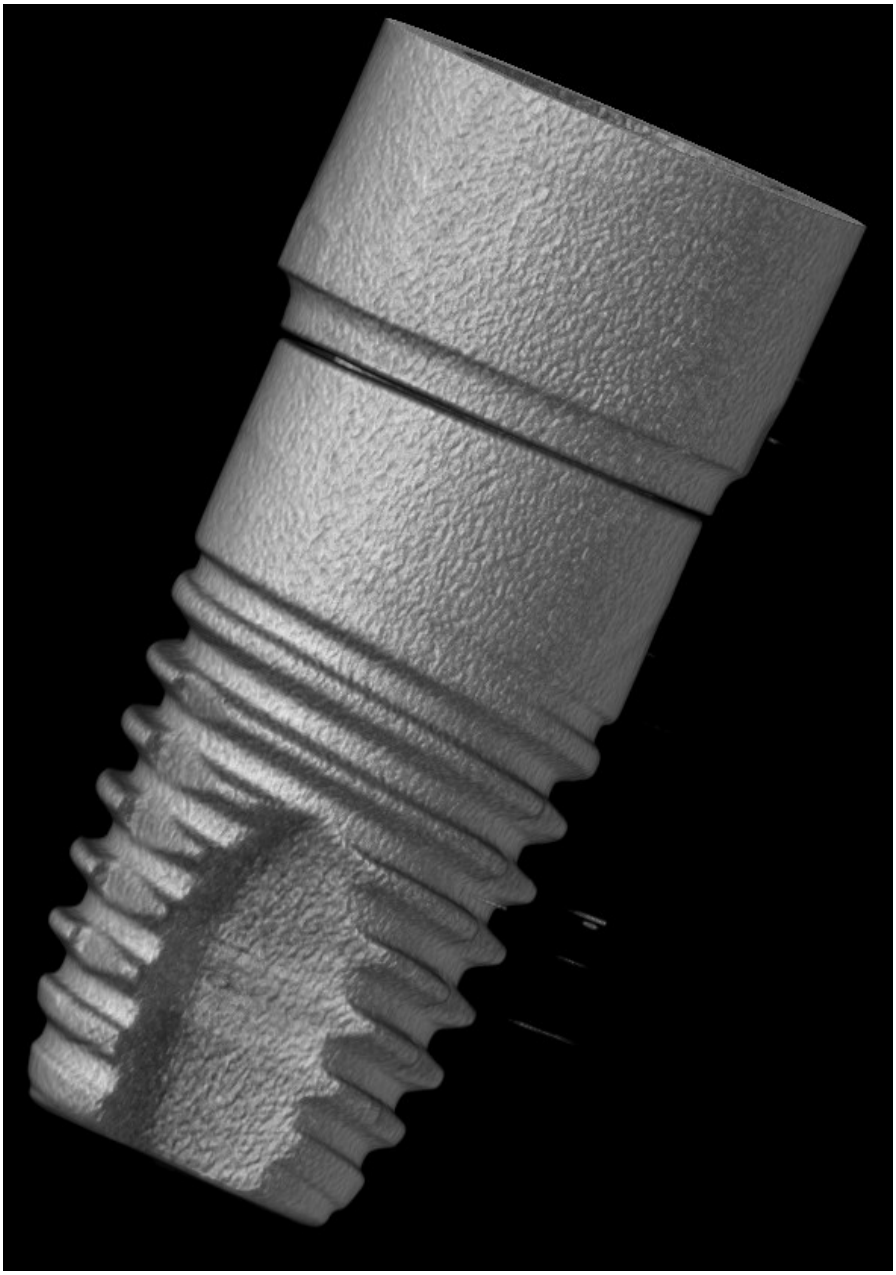


Figure 118: Specimen 3: External View 2 – Generic titanium abutment attached to Neoss ProActive implant

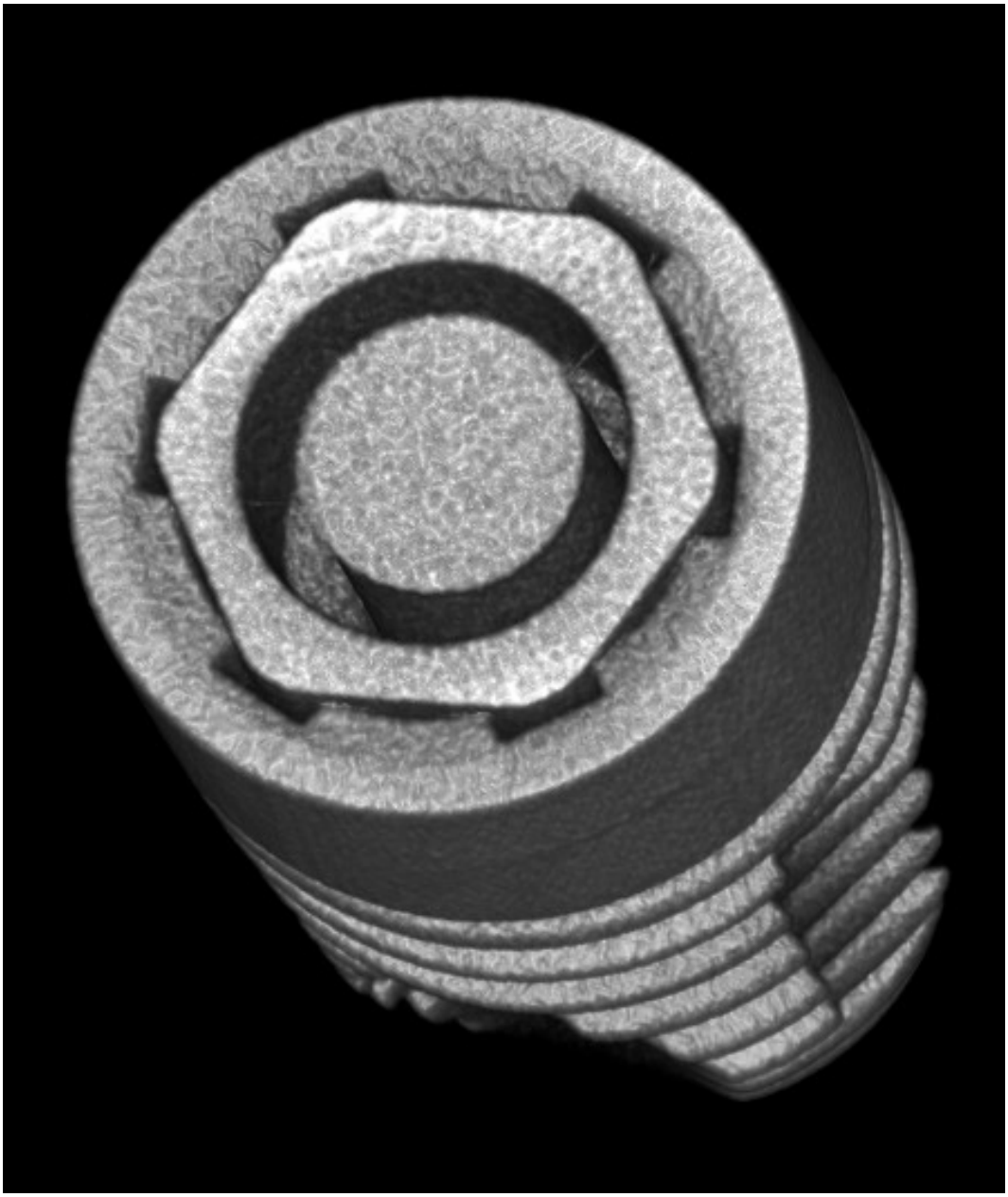


Figure 119: Specimen 3: Cross sectional View 1 (high) -- Generic titanium abutment attached to Neoss ProActive implant

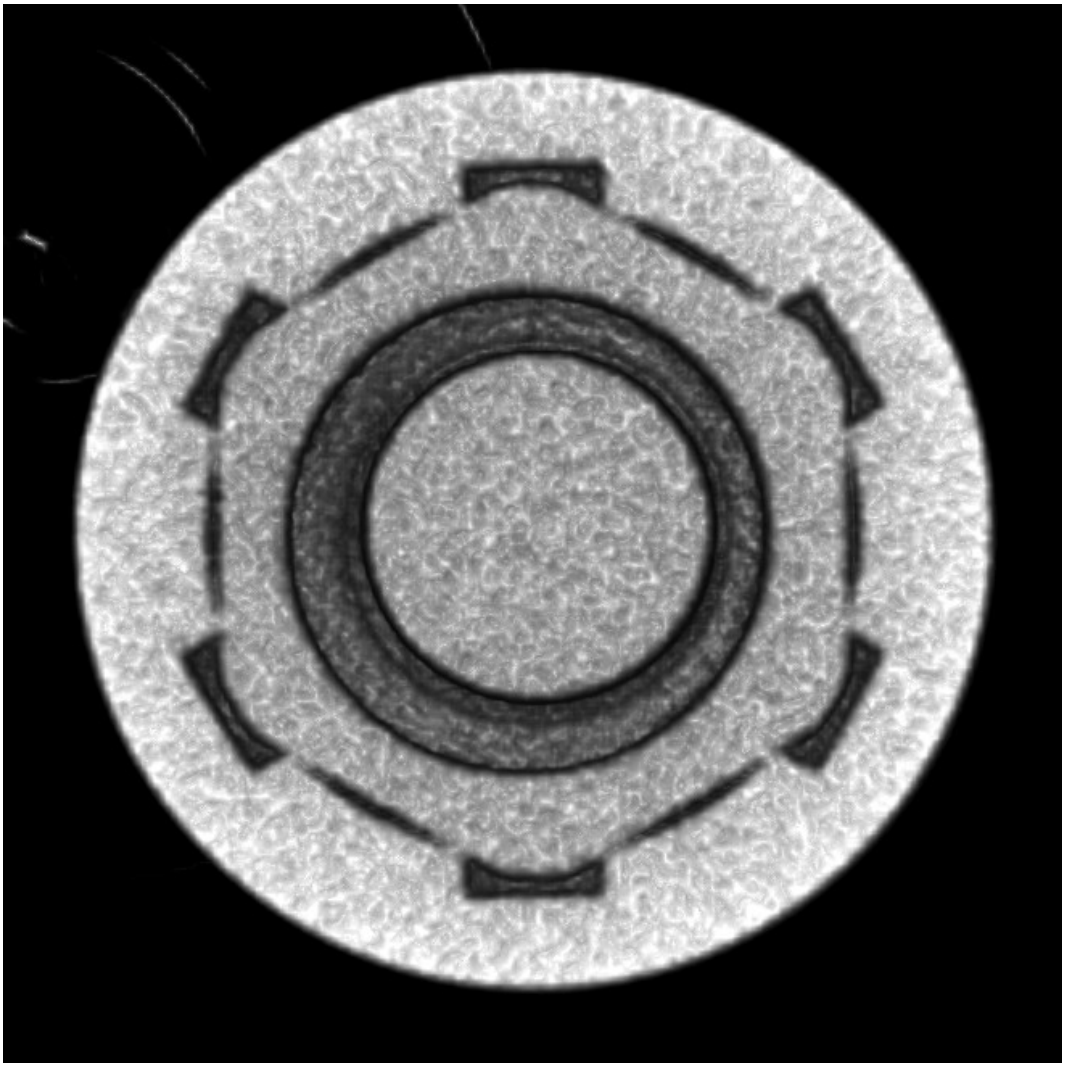


Figure 120: Specimen 3: Cross sectional View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

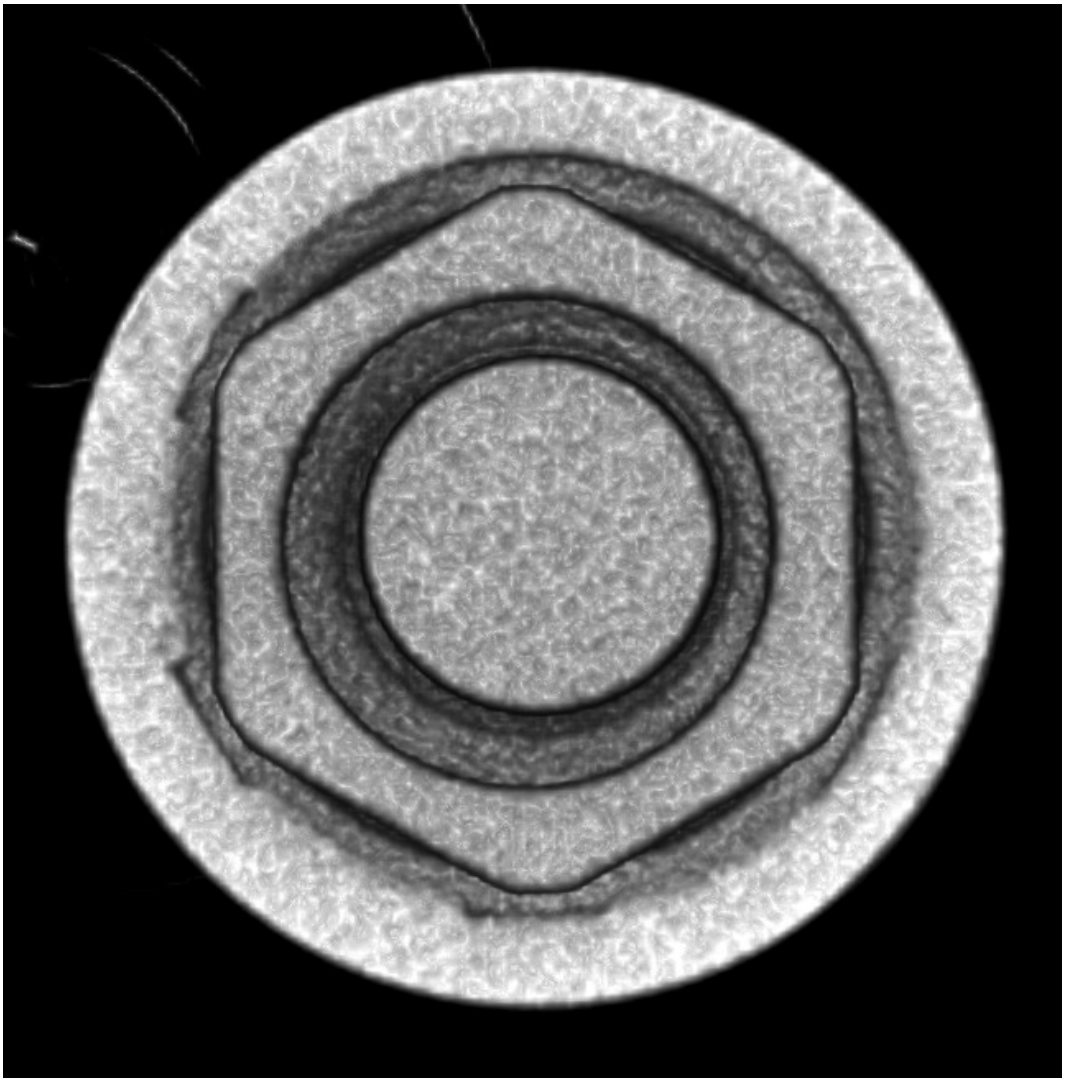


Figure 121: Specimen 3: Cross sectional View 3 (low slice) -- Generic titanium abutment attached to Neoss ProActive implant

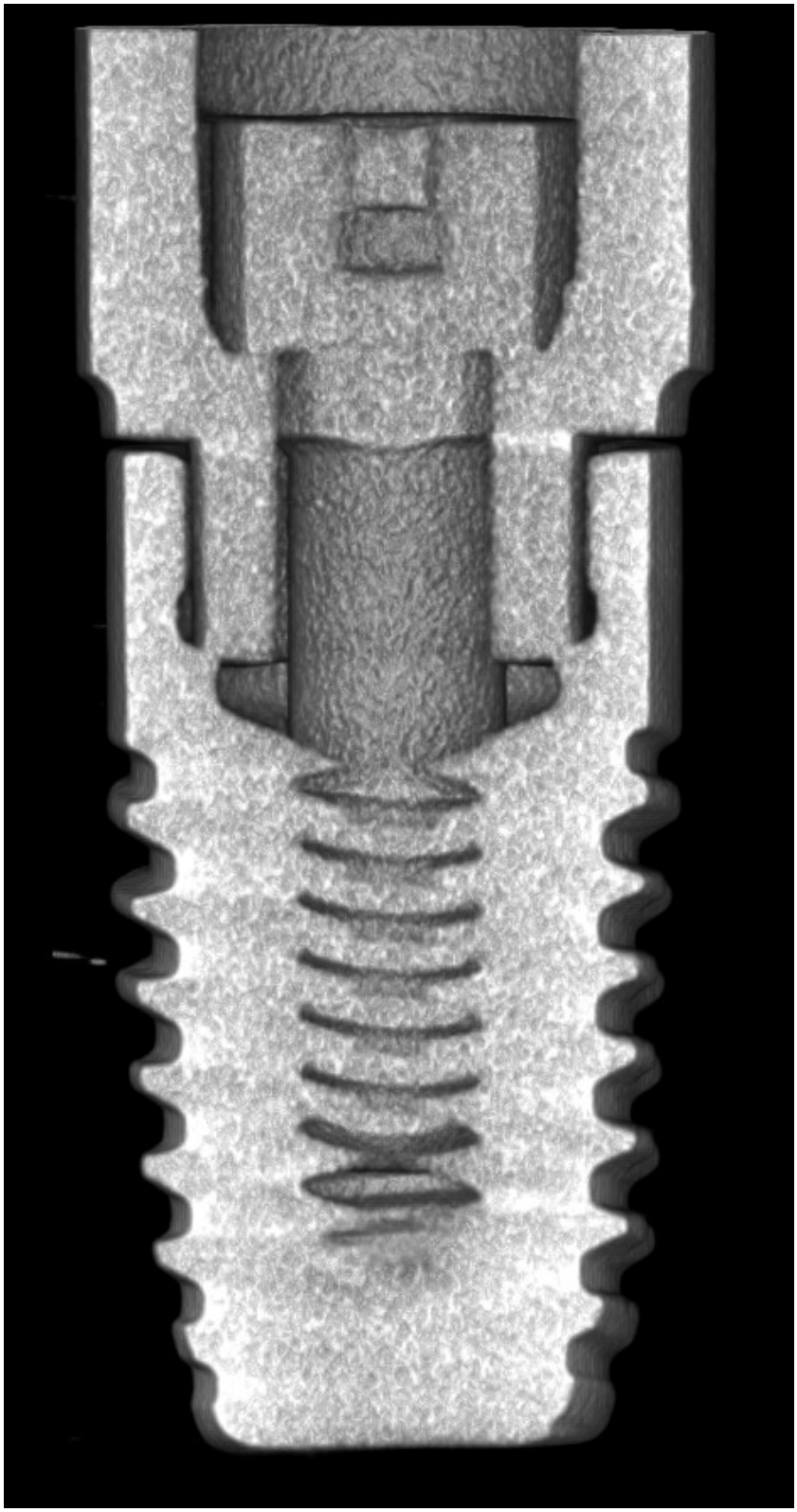


Figure 122: Specimen 3: Coronal View 1 (anterior slice) -- Generic titanium abutment attached to Neoss ProActive implant

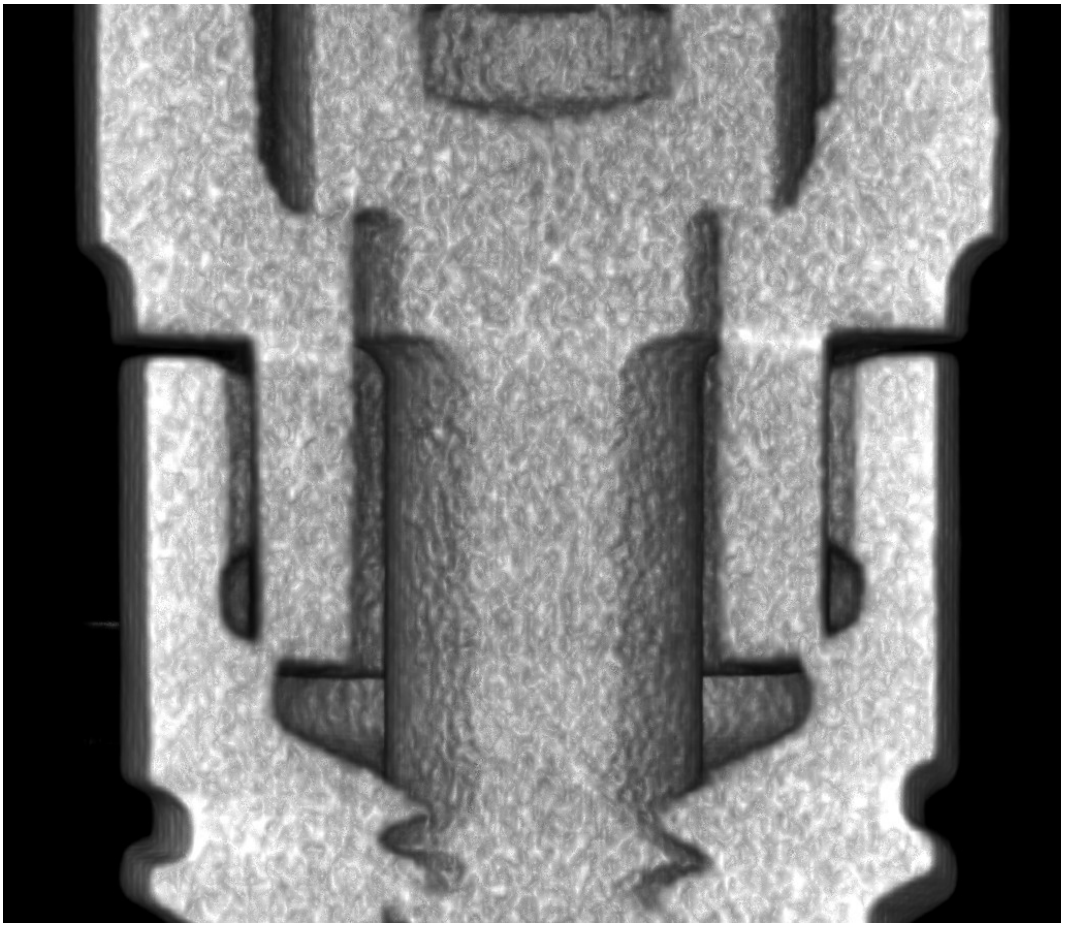


Figure 123: Specimen 3: Coronal View 1a (anterior slice zoom) -- Generic titanium abutment attached to Neoss ProActive implant

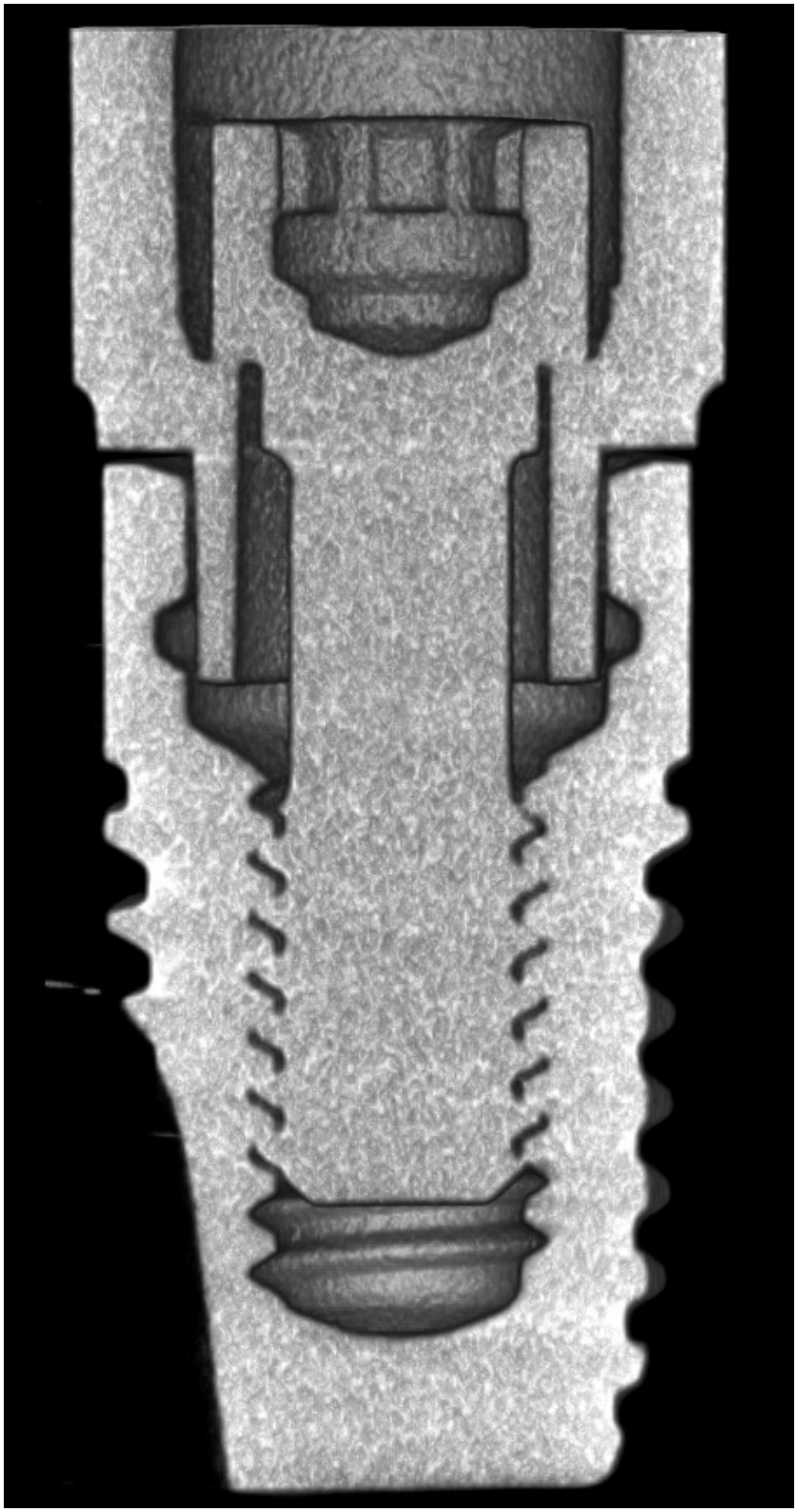


Figure 124: Specimen 3: Coronal View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

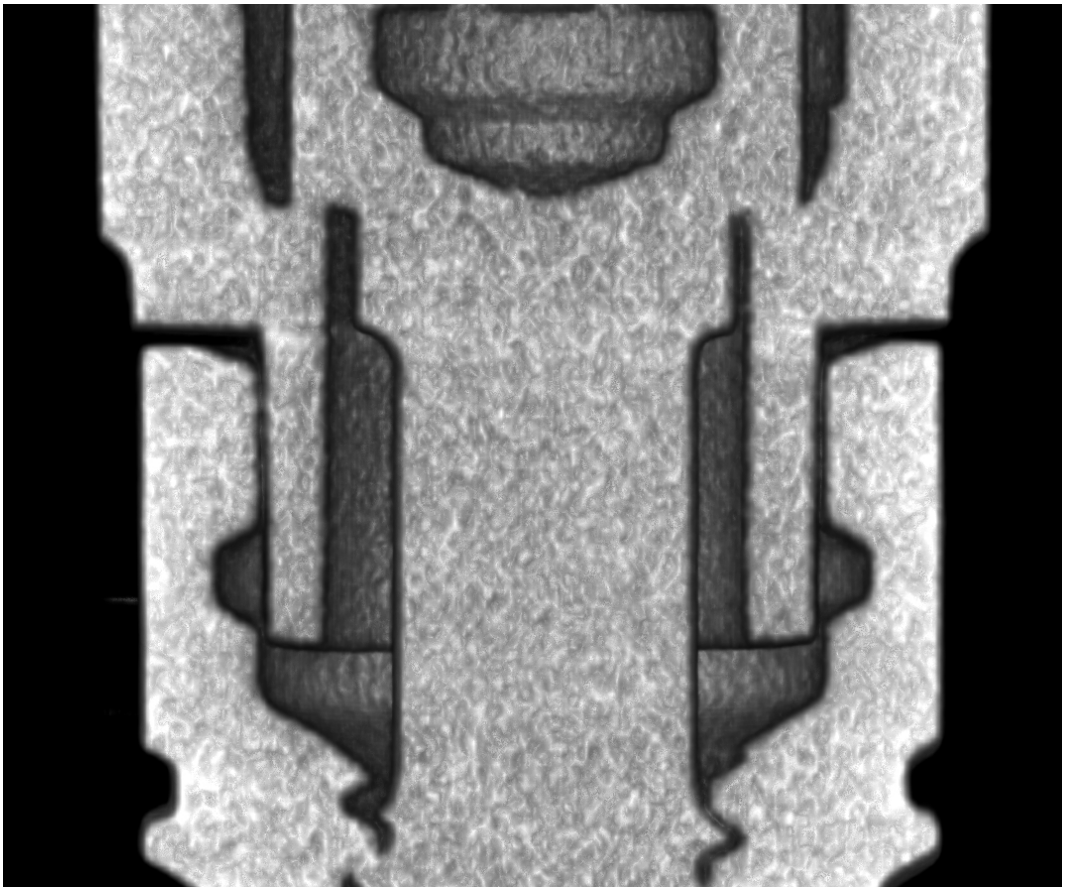


Figure 125: Specimen 3: Coronal View 2a (midpoint slice zoom) -- Generic titanium abutment attached to Neoss ProActive implant

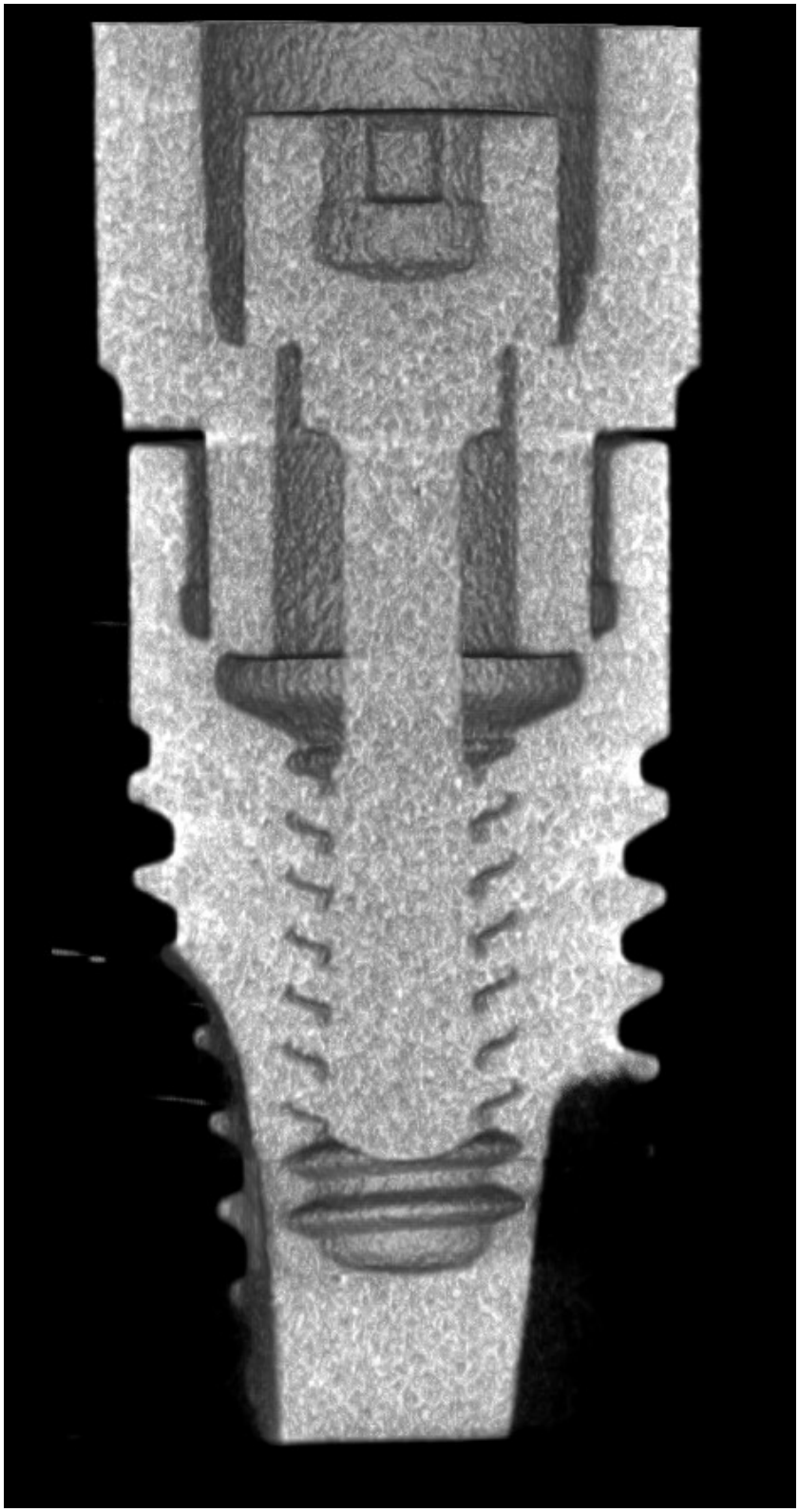


Figure 126: *Specimen 3: Coronal View 3 (posterior slice) -- Generic titanium abutment attached to Neoss ProActive implant*

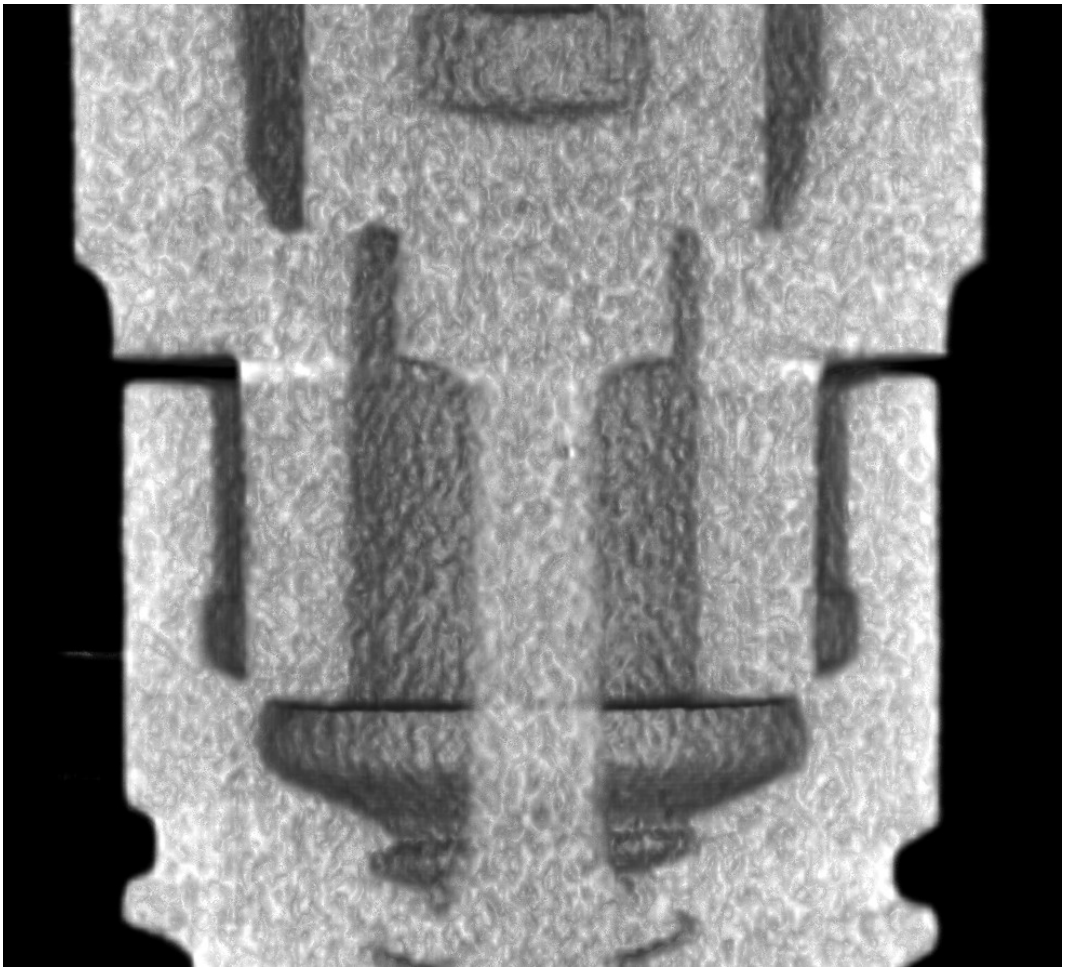


Figure 127: Specimen 3: Coronal View 3a (posterior slice zoom) -- Generic titanium abutment attached to Neoss ProActive implant

Specimen 4

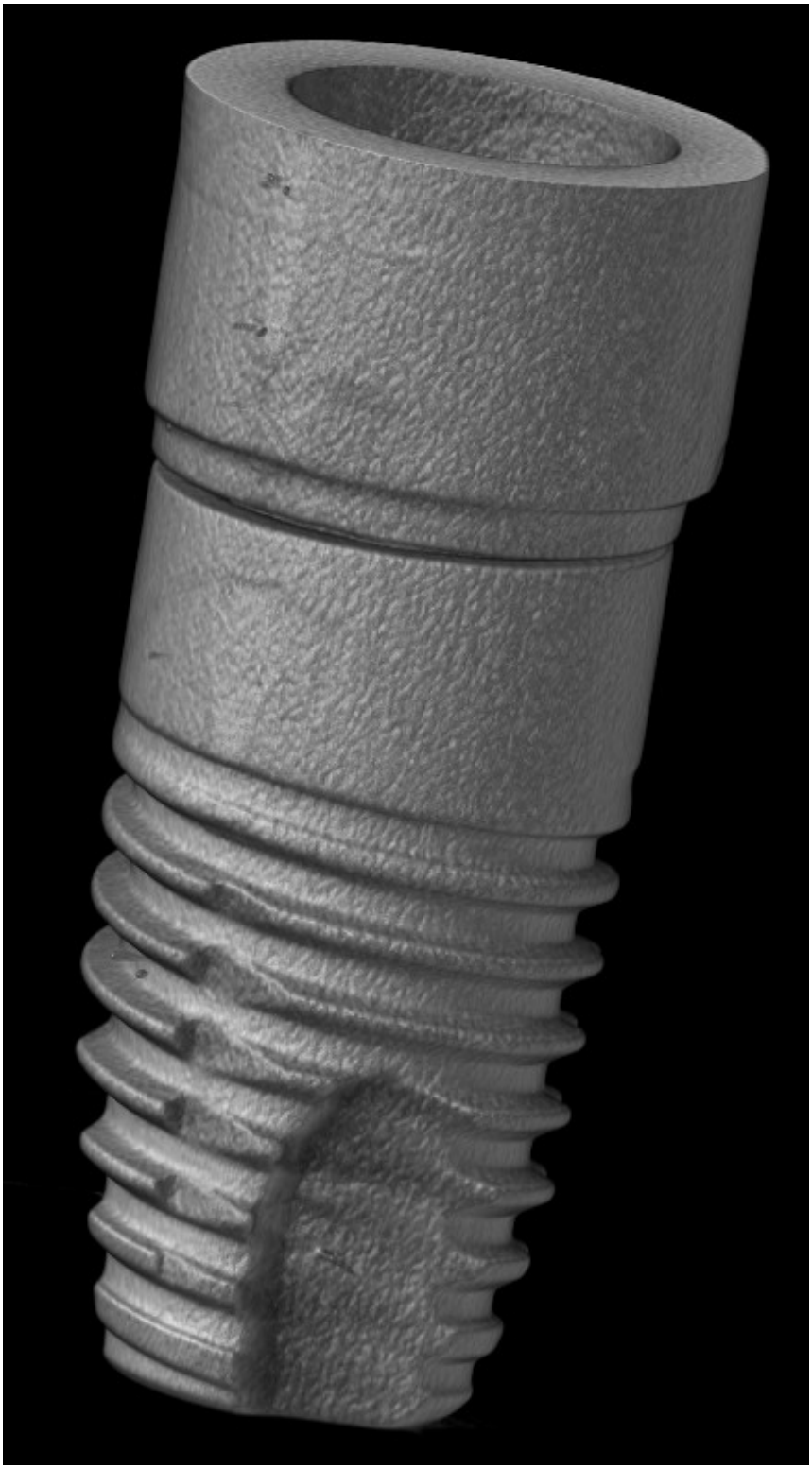


Figure 128: Specimen 4: External View 1 – Generic titanium abutment attached to Neoss ProActive implant

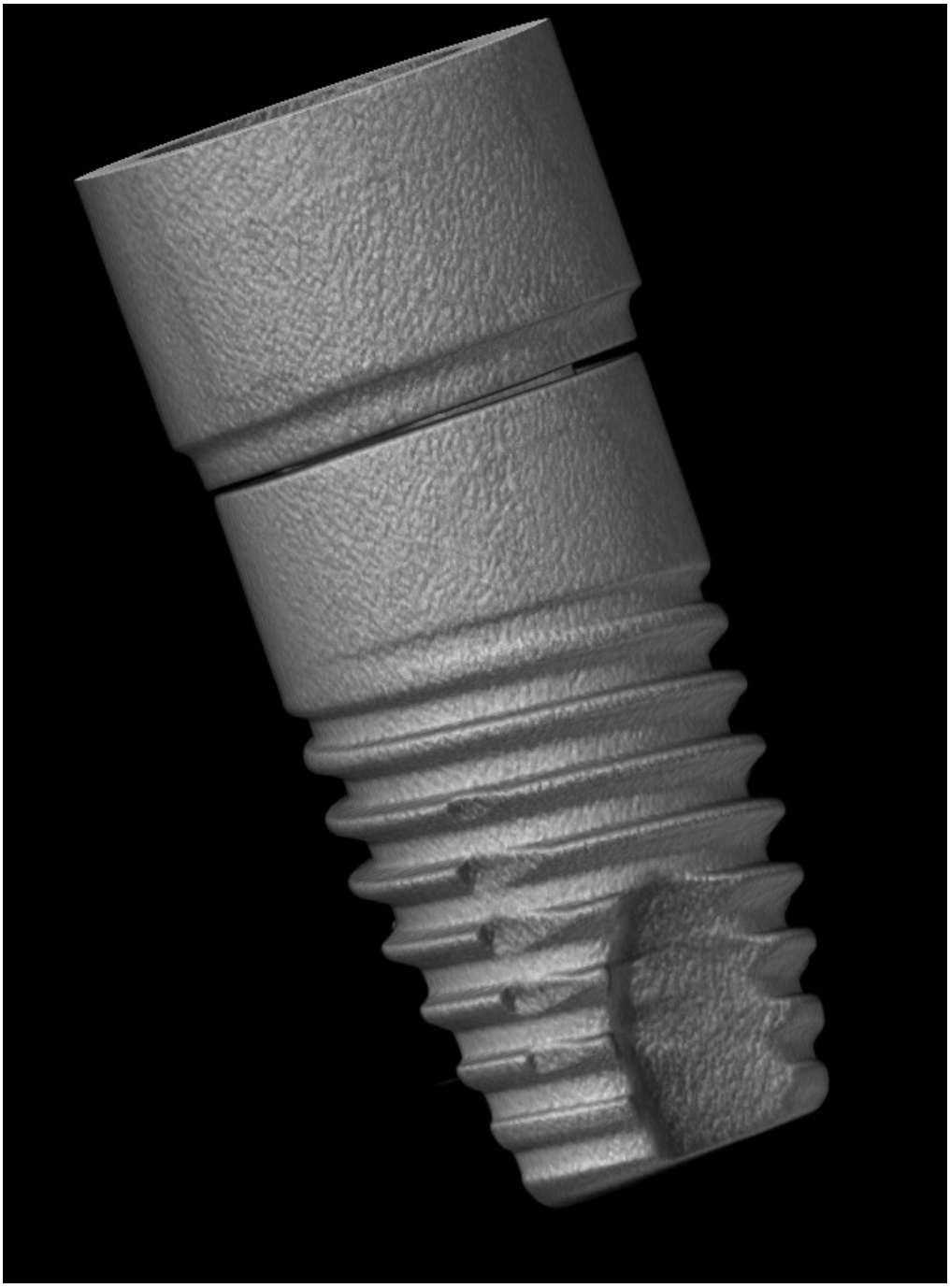


Figure 129: Specimen 4: External View 2 – Generic titanium abutment attached to Neoss ProActive implant

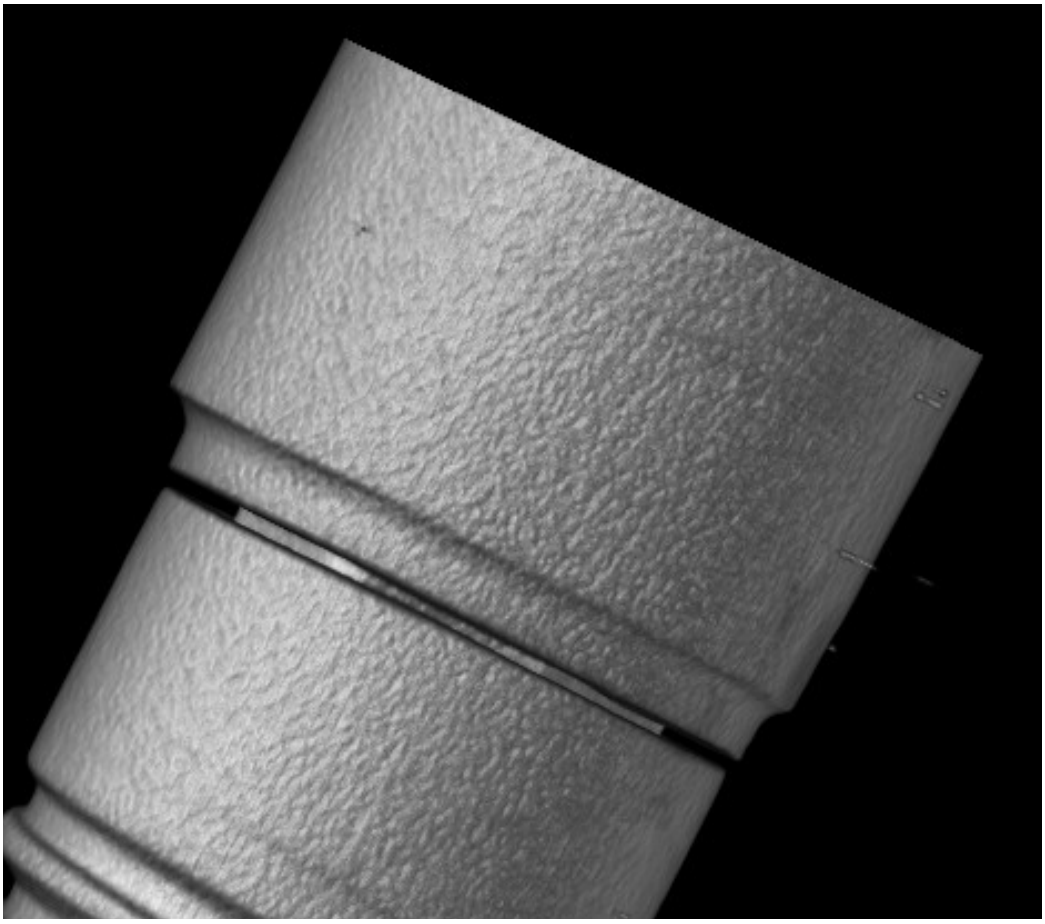


Figure 130: Specimen 4: External View 3 – Generic titanium abutment attached to Neoss ProActive implant

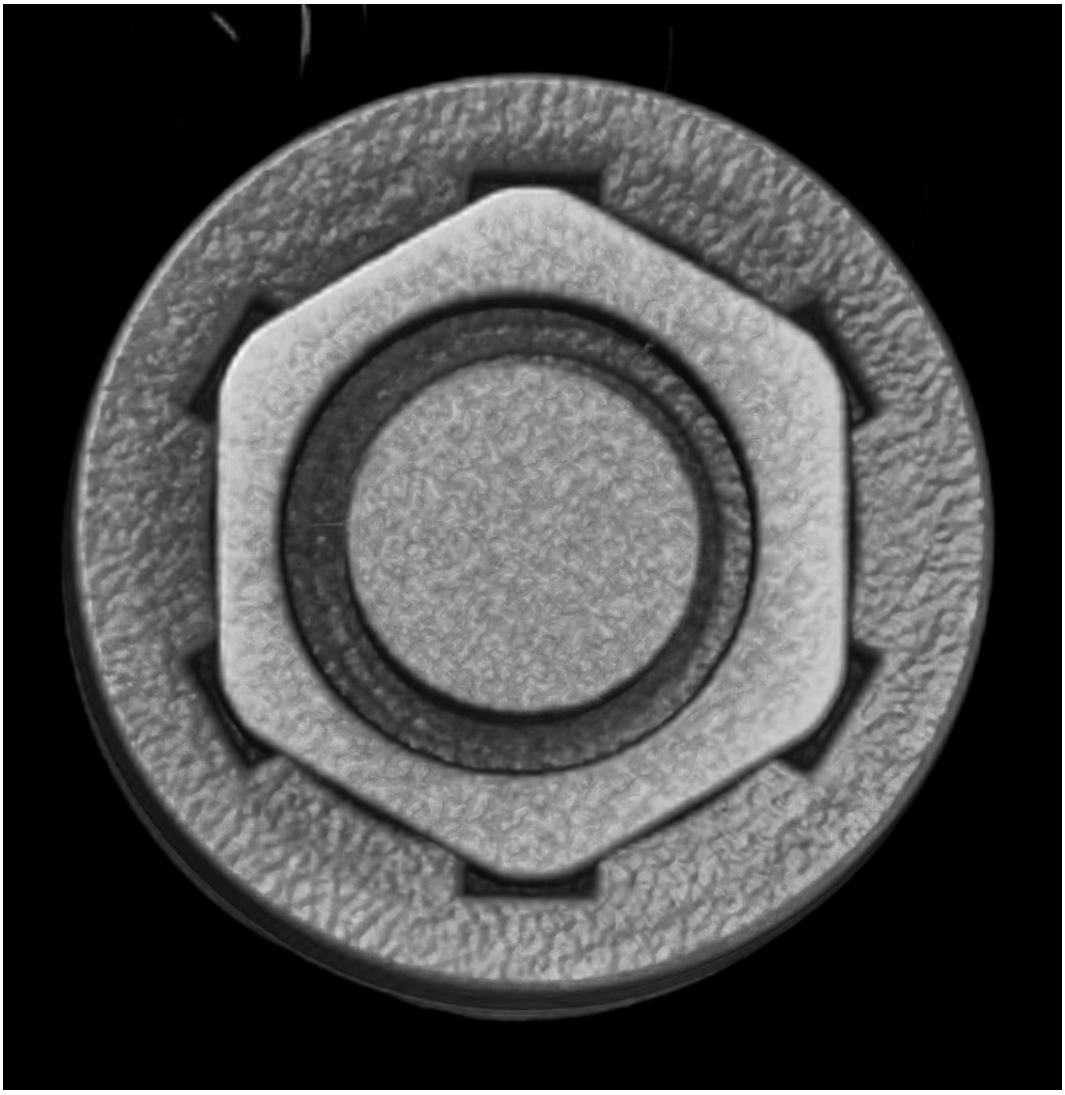


Figure 131: Specimen 4: Cross sectional View 1 (high) -- Generic titanium abutment attached to Neoss ProActive implant

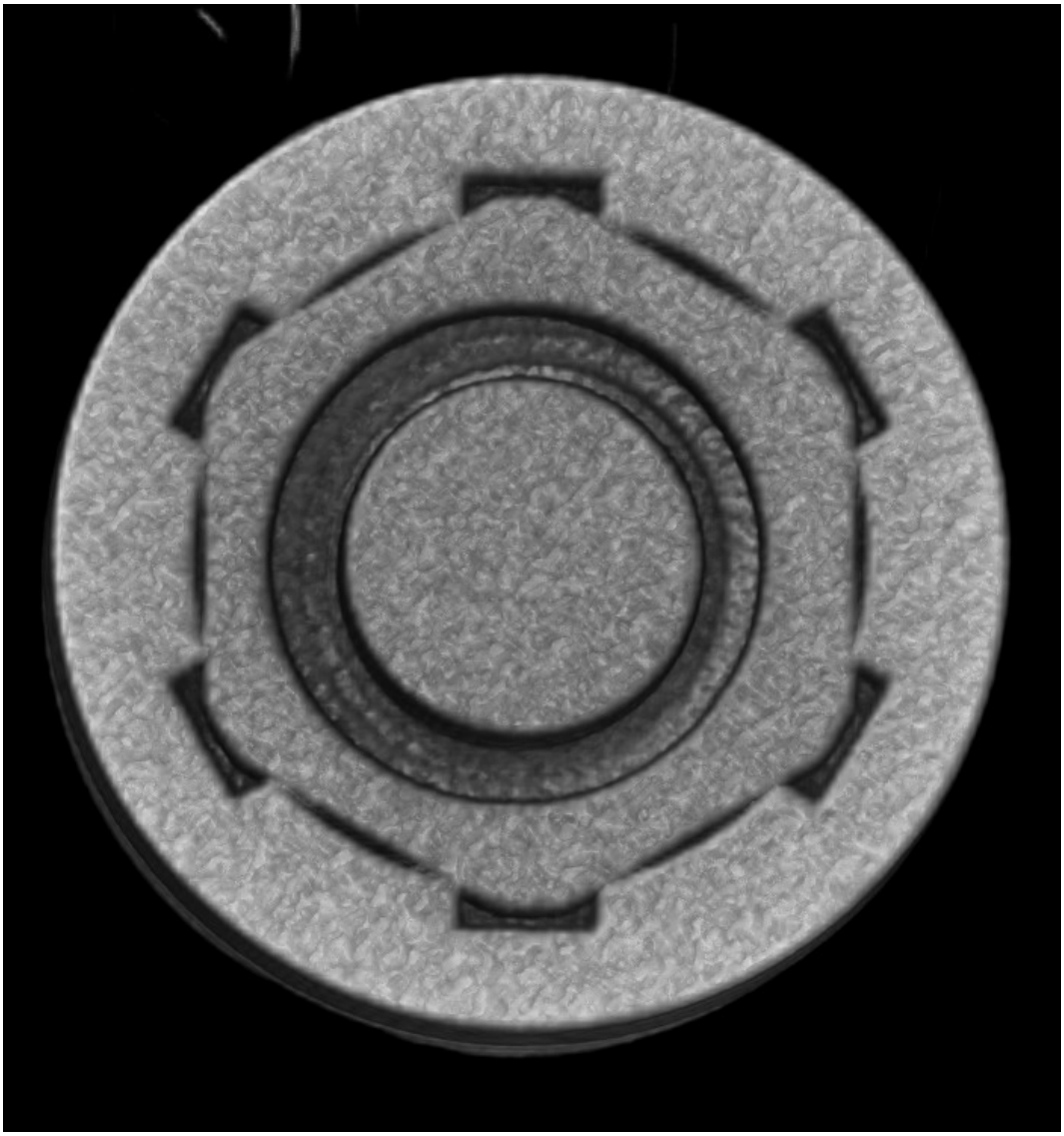


Figure 132: Specimen 4: Cross sectional View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

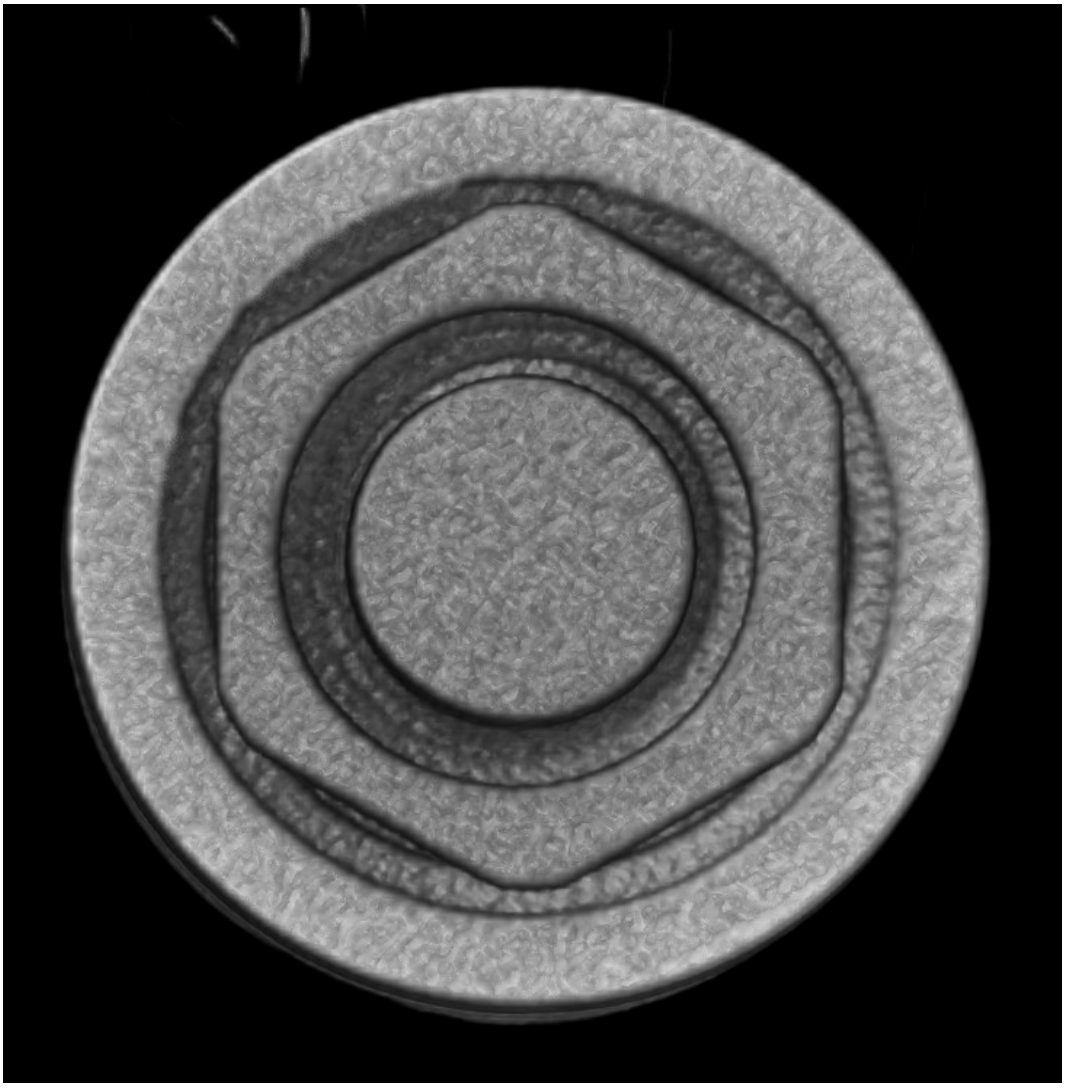


Figure 133: Specimen 4: Cross sectional View 3 (low slice) -- Generic titanium abutment attached to Neoss ProActive implant

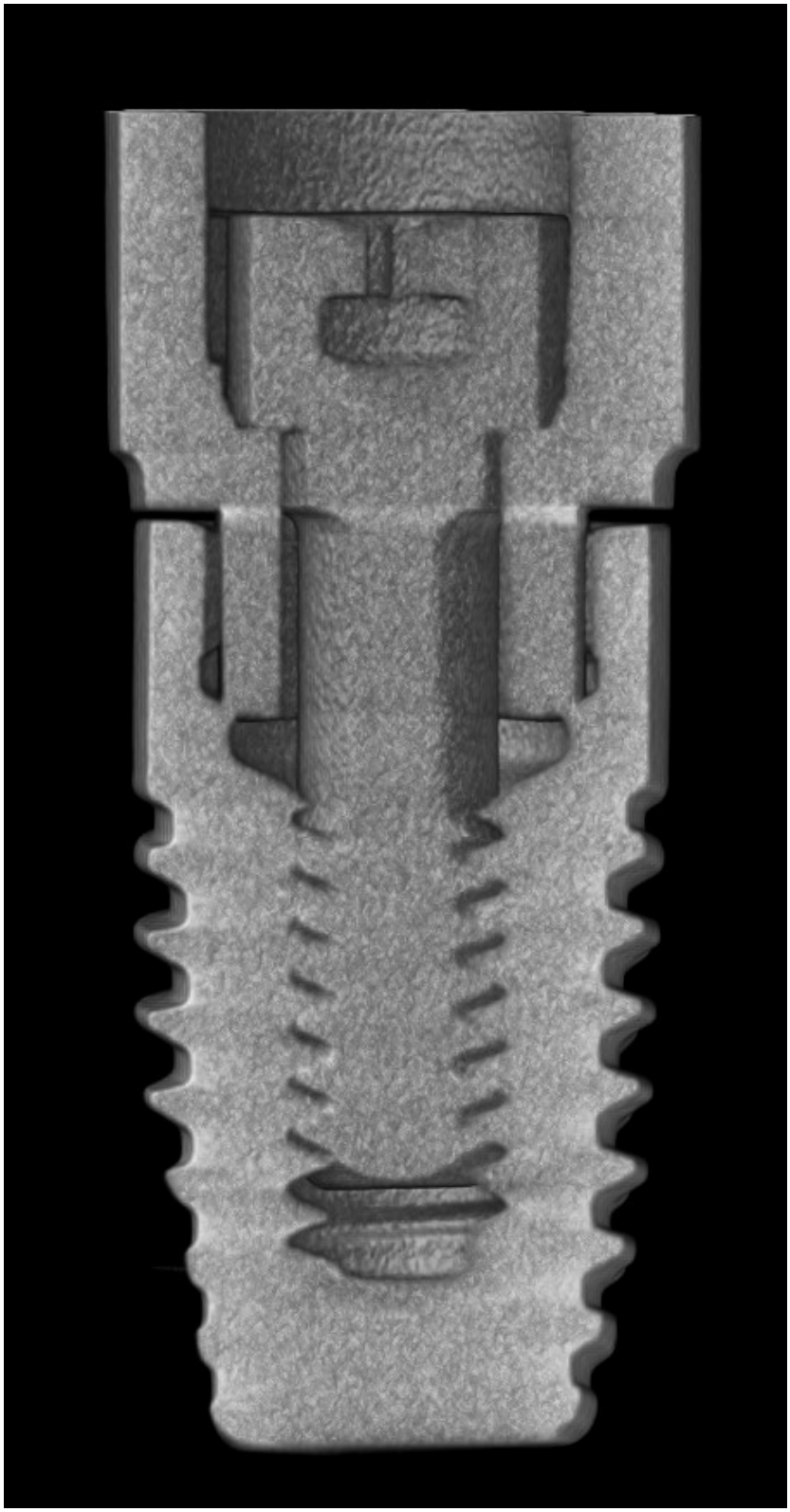


Figure 134: *Specimen 4: Coronal View 1 (anterior slice) -- Generic titanium abutment attached to Neoss ProActive implant*

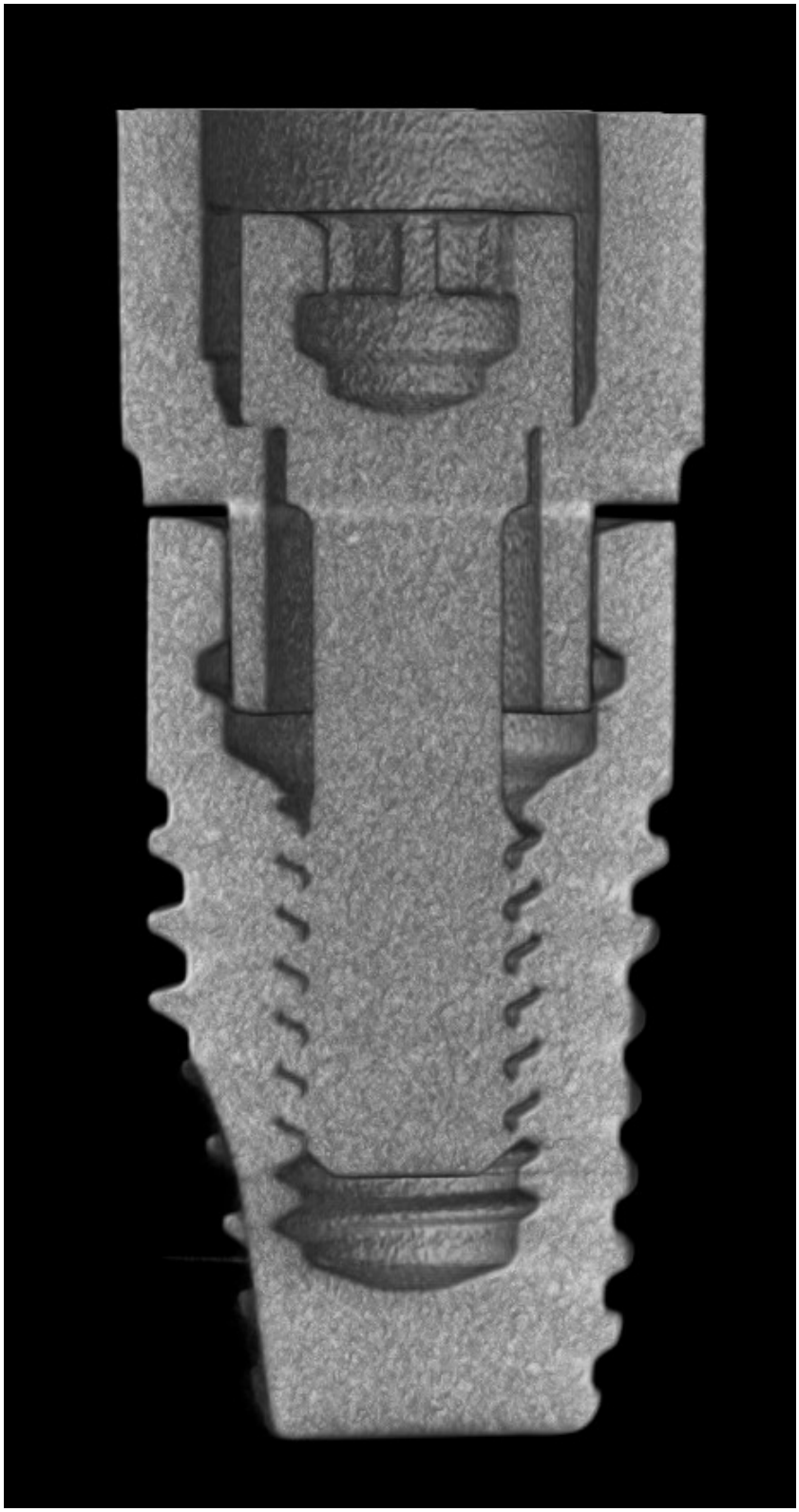


Figure 135: Specimen 4: Coronal View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

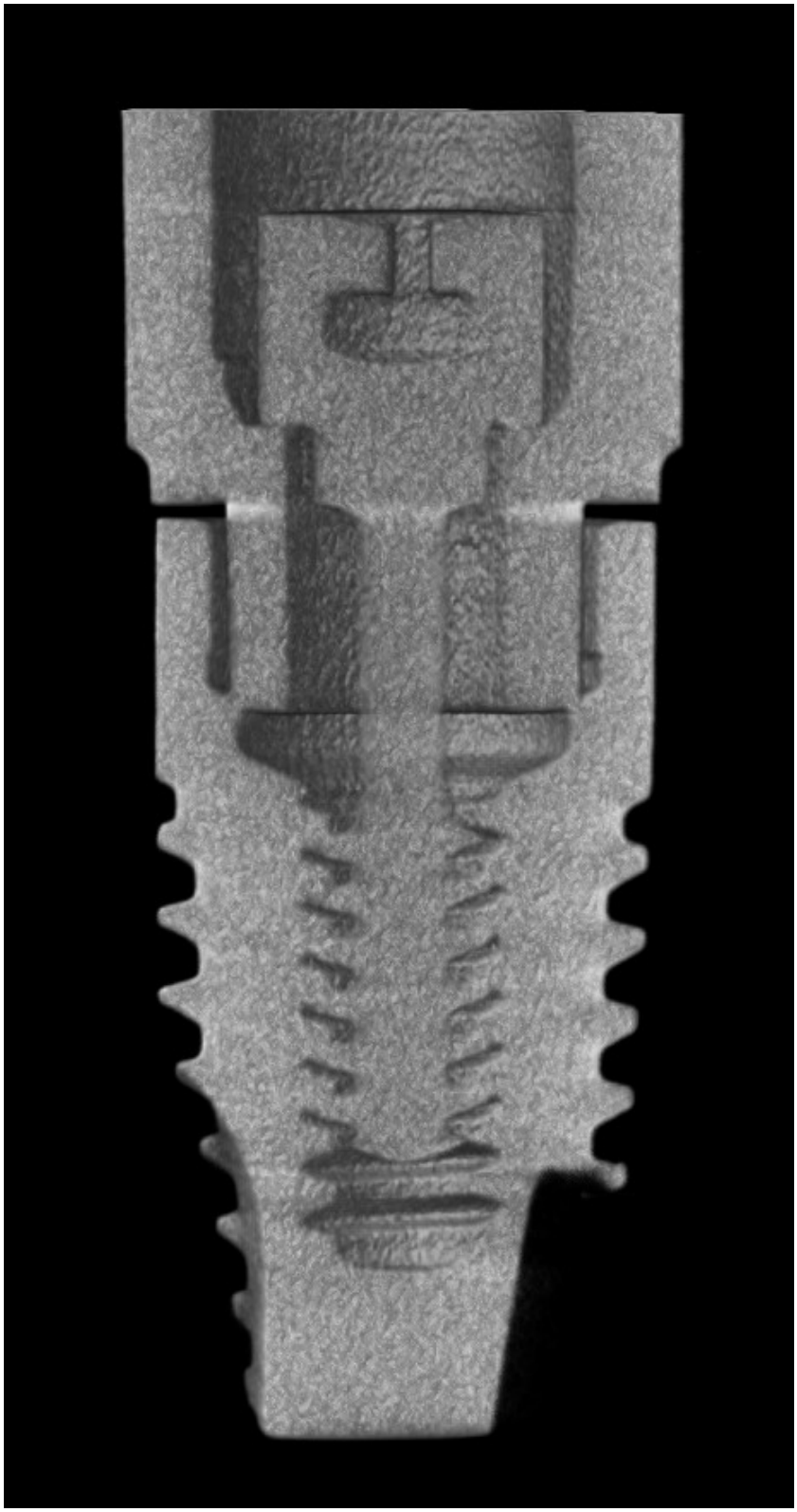


Figure 136: *Specimen 4: Coronal View 3 (posterior slice) -- Generic titanium abutment attached to Neoss ProActive implant*

Specimen 5

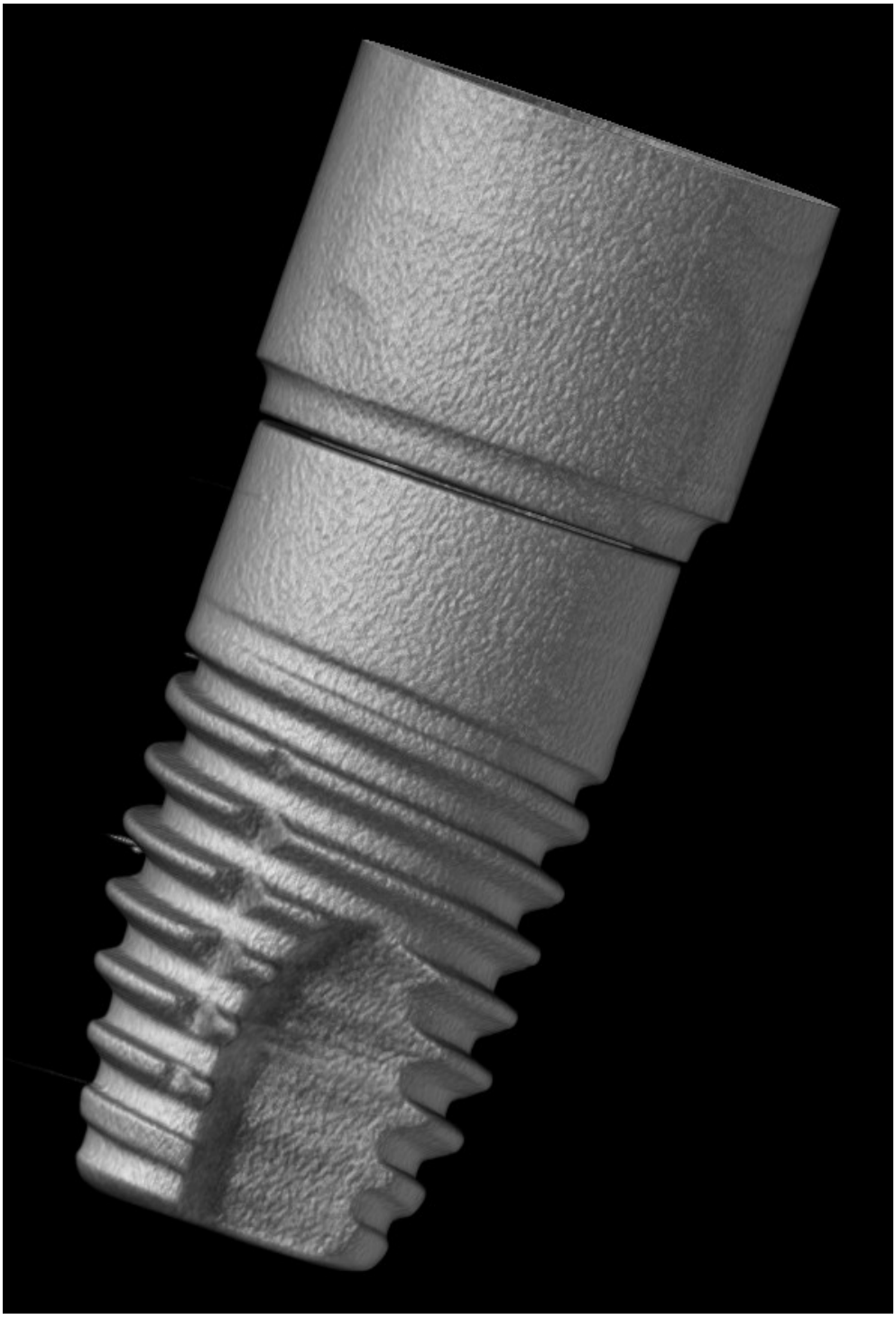


Figure 137: Specimen 5: External View 1 – Generic titanium abutment attached to Neoss ProActive implant

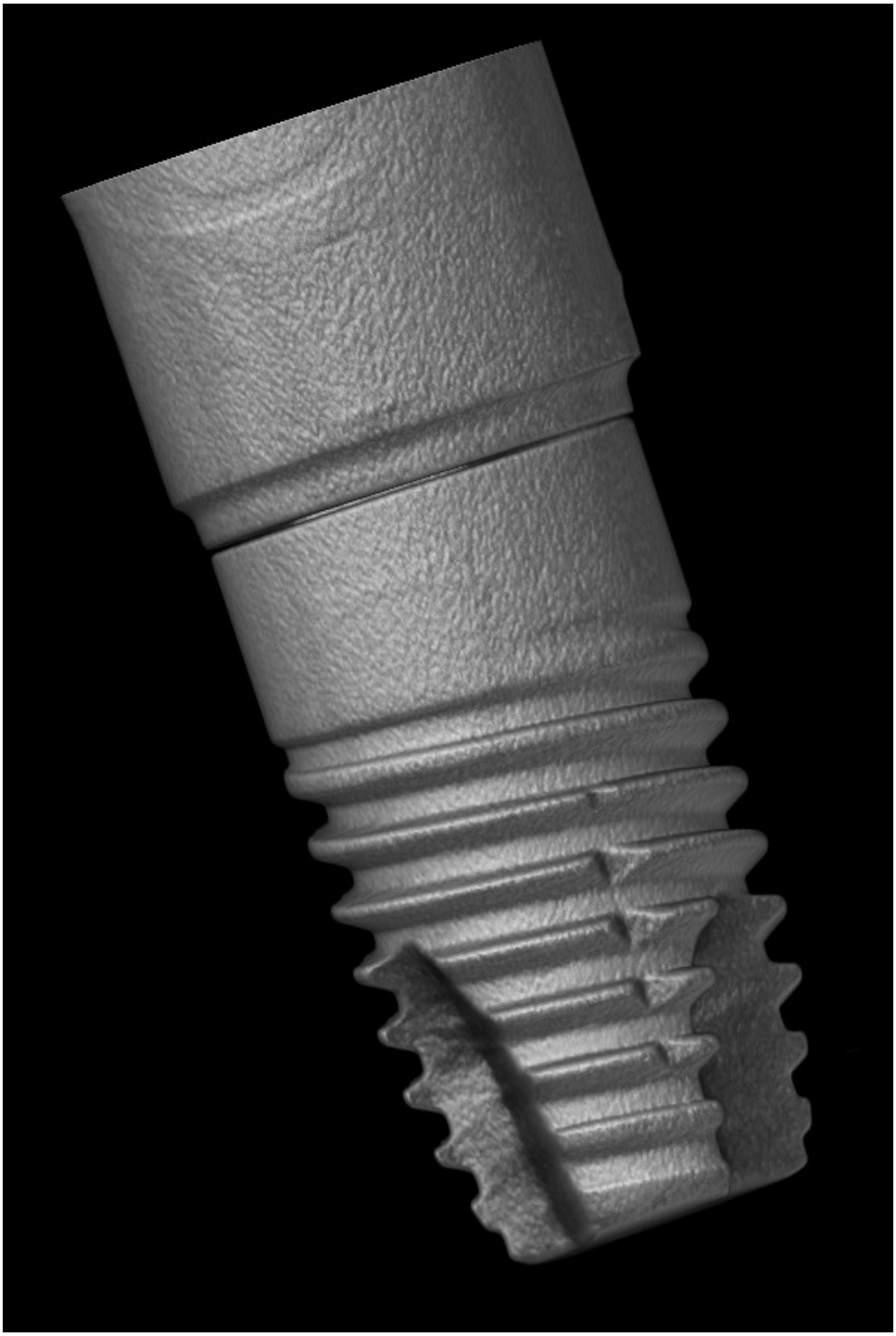


Figure 138: Specimen 5: External View 2 – Generic titanium abutment attached to Neoss ProActive implant

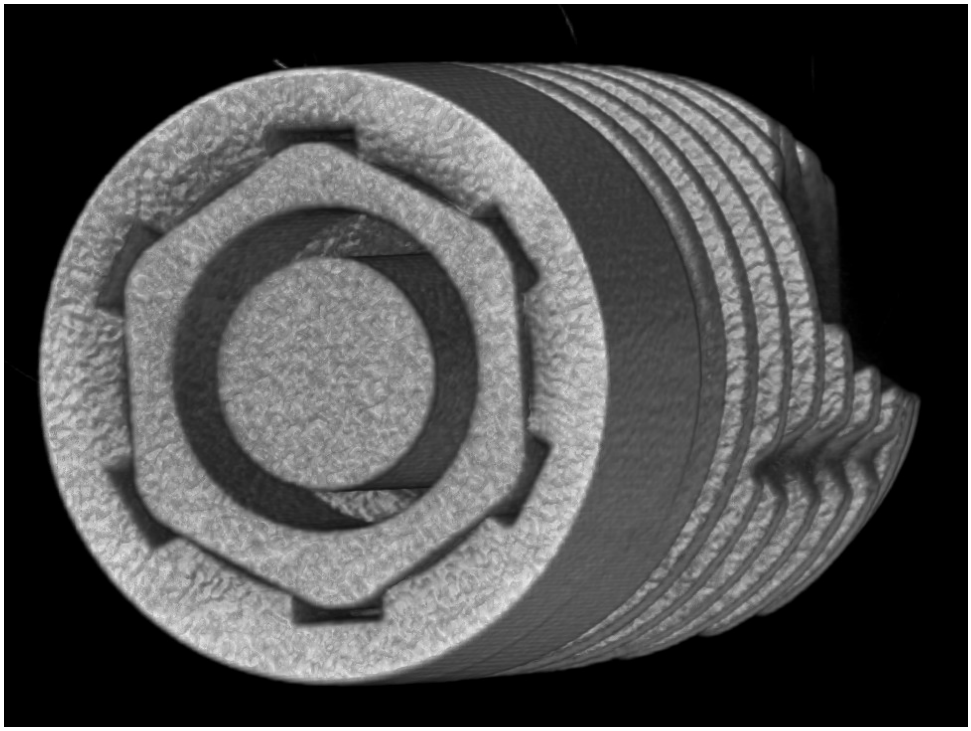


Figure 139: Specimen 5: Cross sectional transverse View 1 (high) -- Generic titanium abutment attached to Neoss ProActive implant

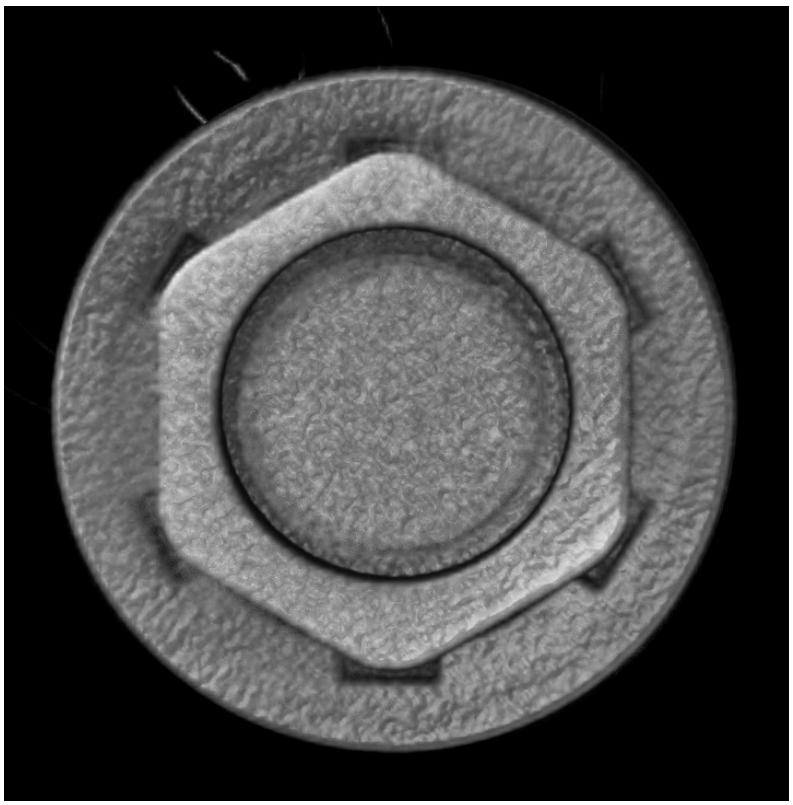


Figure 140: Specimen 5: Cross sectional View 1a (high) -- Generic titanium abutment attached to Neoss ProActive implant

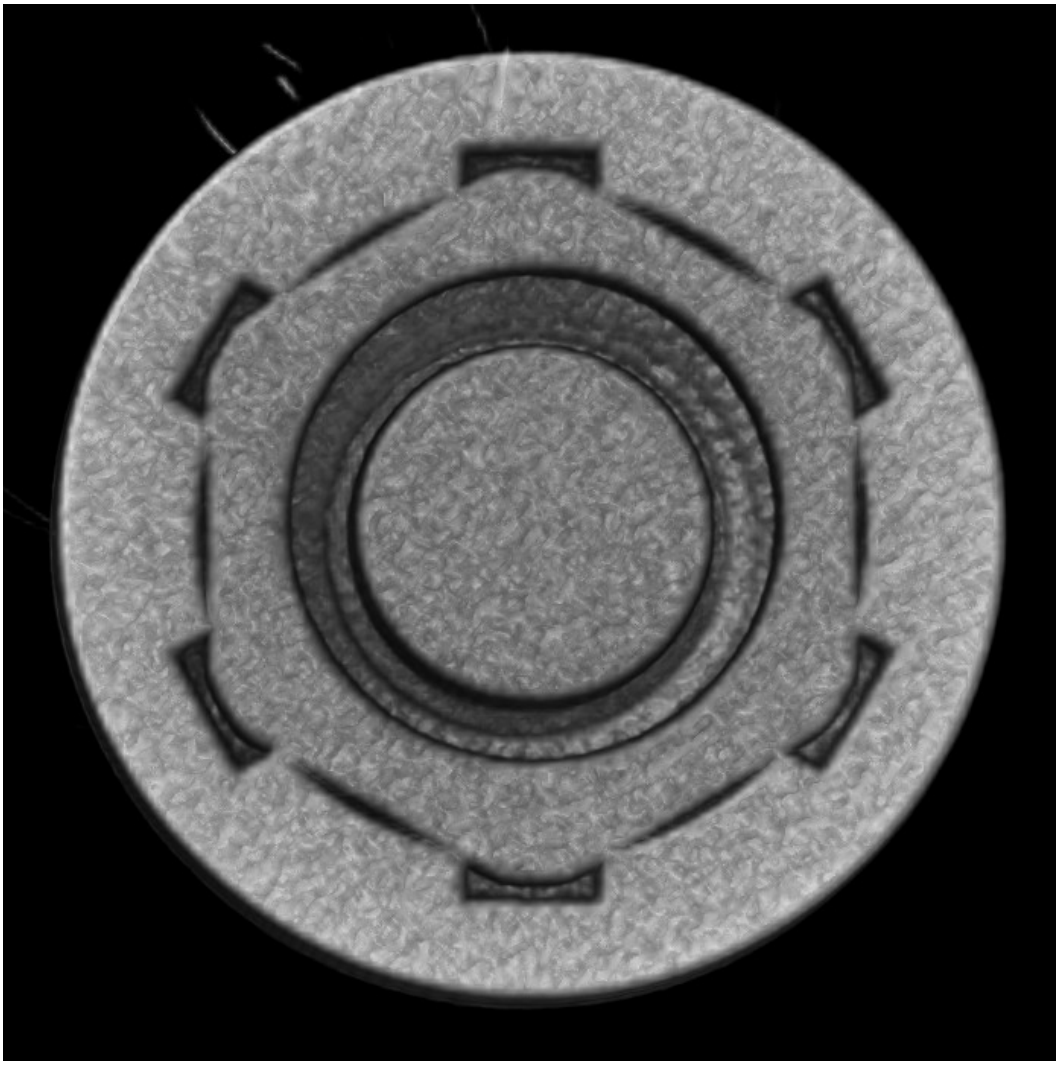


Figure 141: Specimen 5: Cross sectional View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

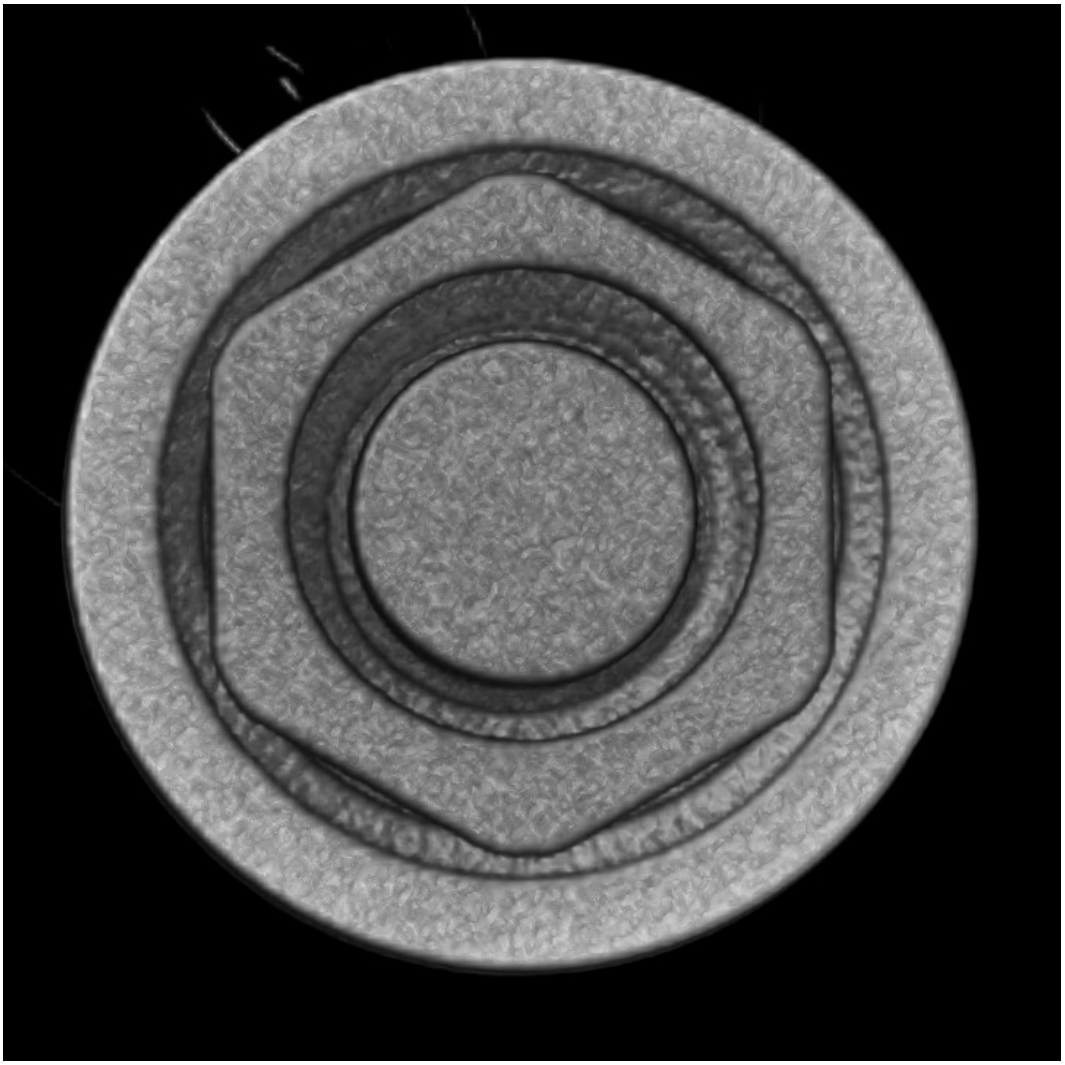


Figure 142: Specimen 5: Cross sectional View 3 (low slice) -- Generic titanium abutment attached to Neoss ProActive implant

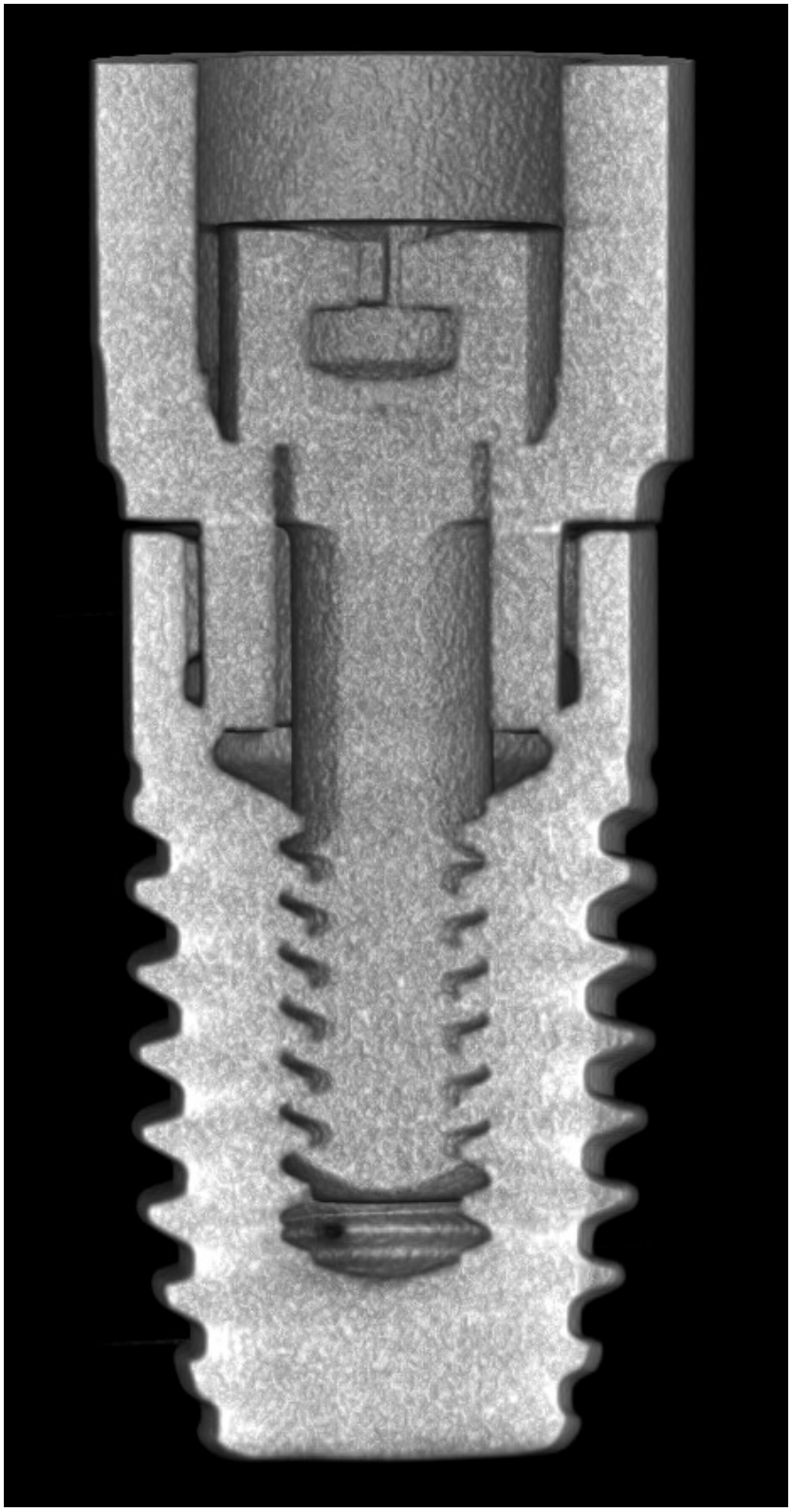


Figure 143: Specimen 5: Coronal View 1 (anterior slice) -- Generic titanium abutment attached to Neoss ProActive implant

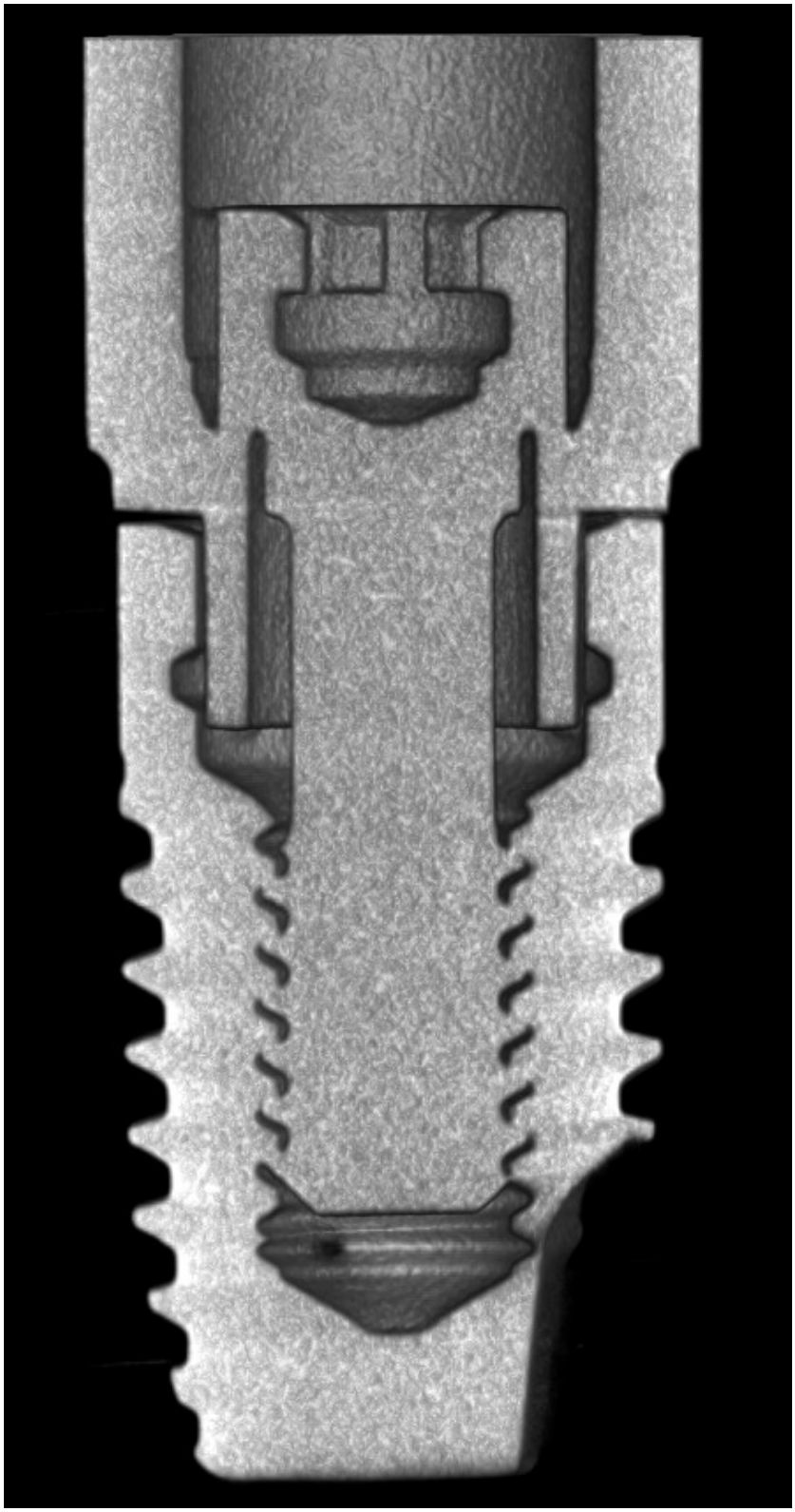


Figure 144: Specimen 5: Coronal View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

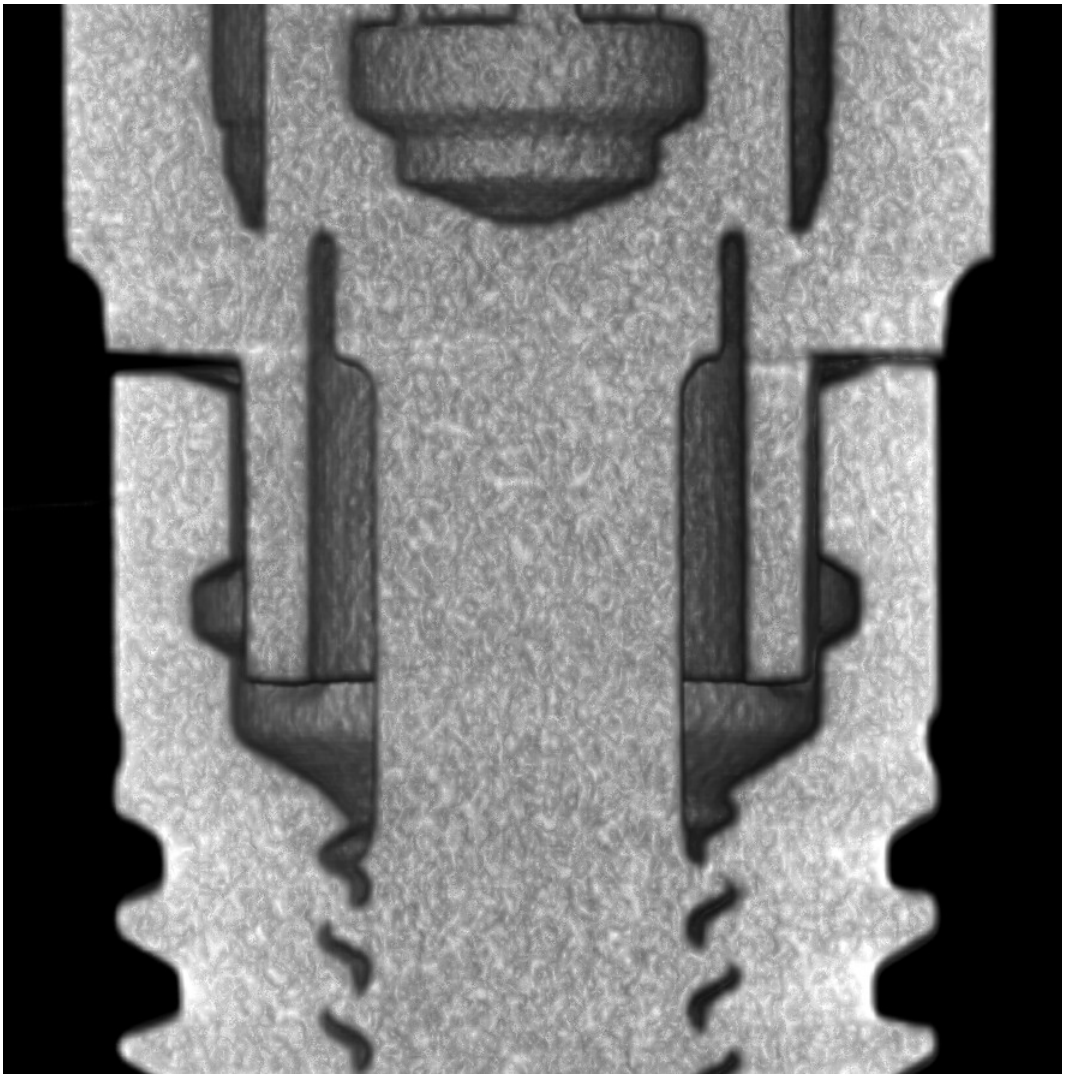


Figure 145: Specimen 5: Coronal View 2a zoom (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

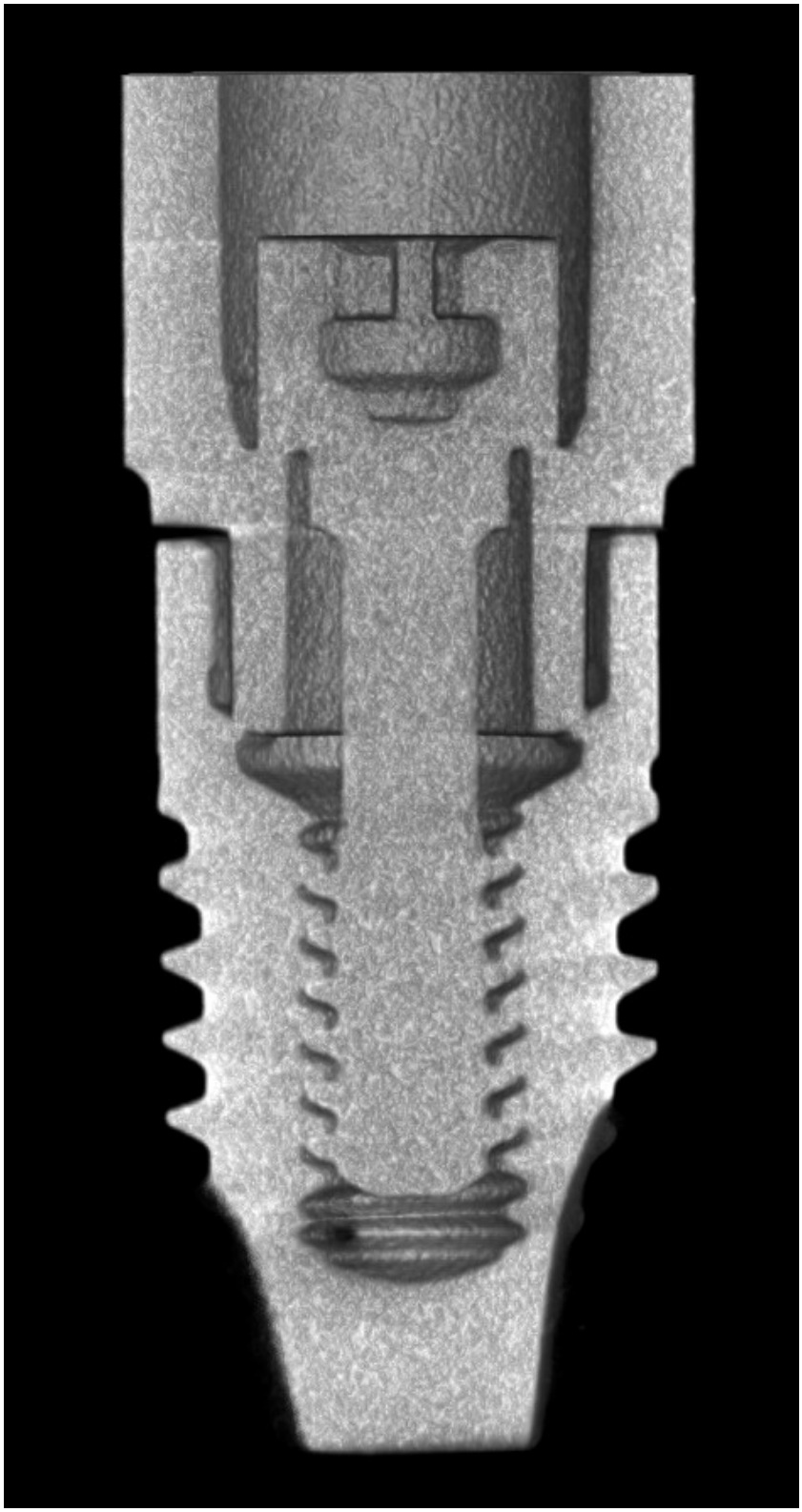


Figure 146: Specimen 5: Coronal View 3 (posterior slice) -- Generic titanium abutment attached to Neoss ProActive implant

Specimen 6

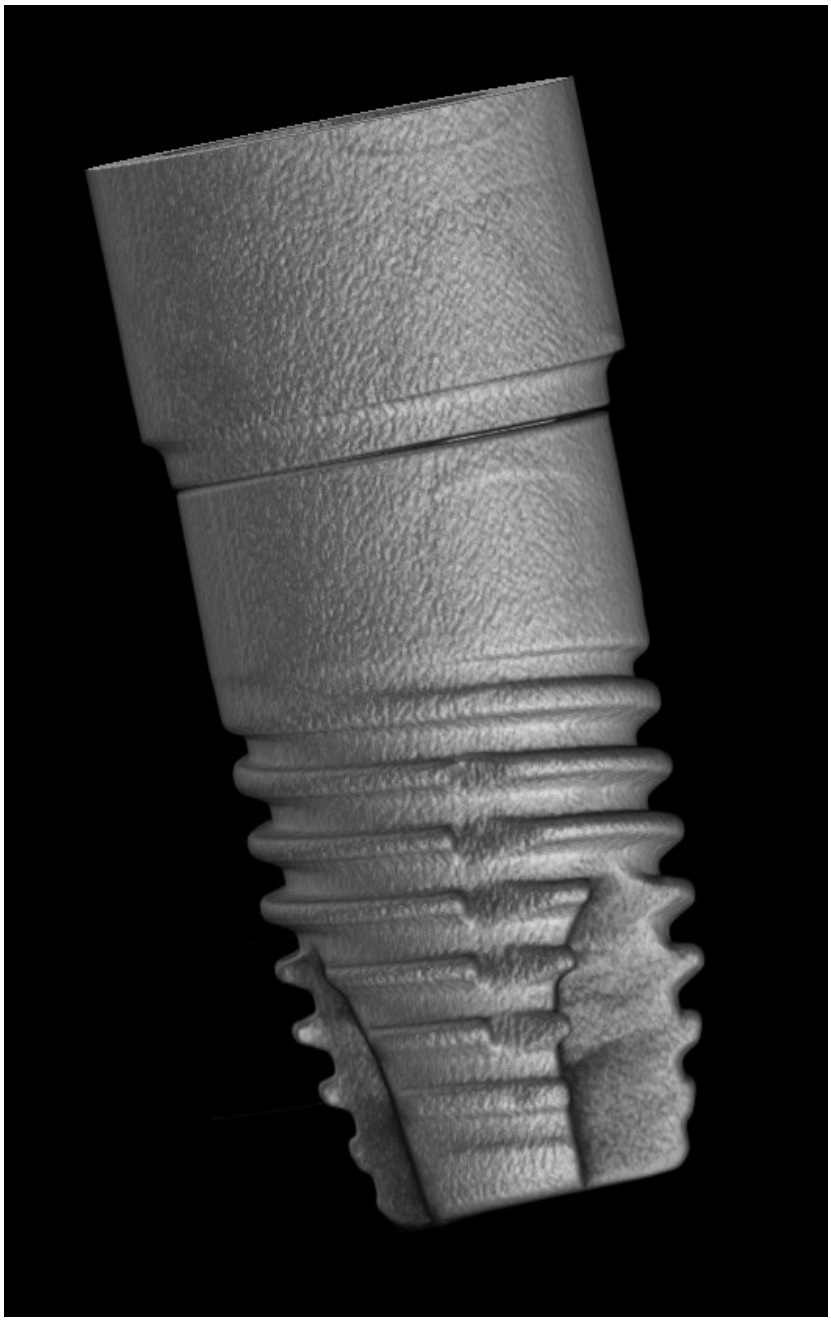


Figure 147: Specimen 6: External View 1 – Generic titanium abutment attached to Neoss ProActive implant

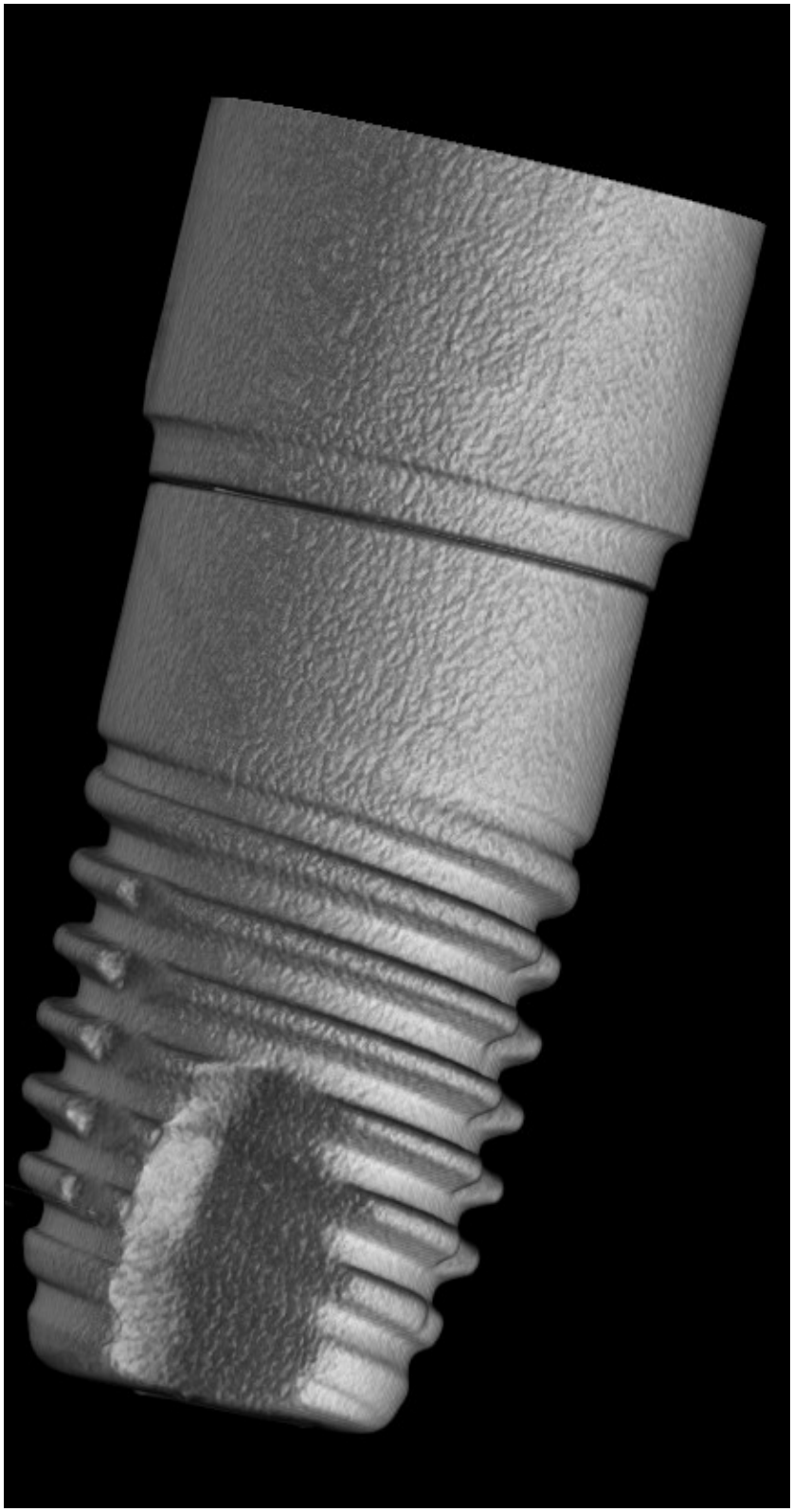


Figure 148: Specimen 6: External View 2 – Generic titanium abutment attached to Neoss ProActive implant

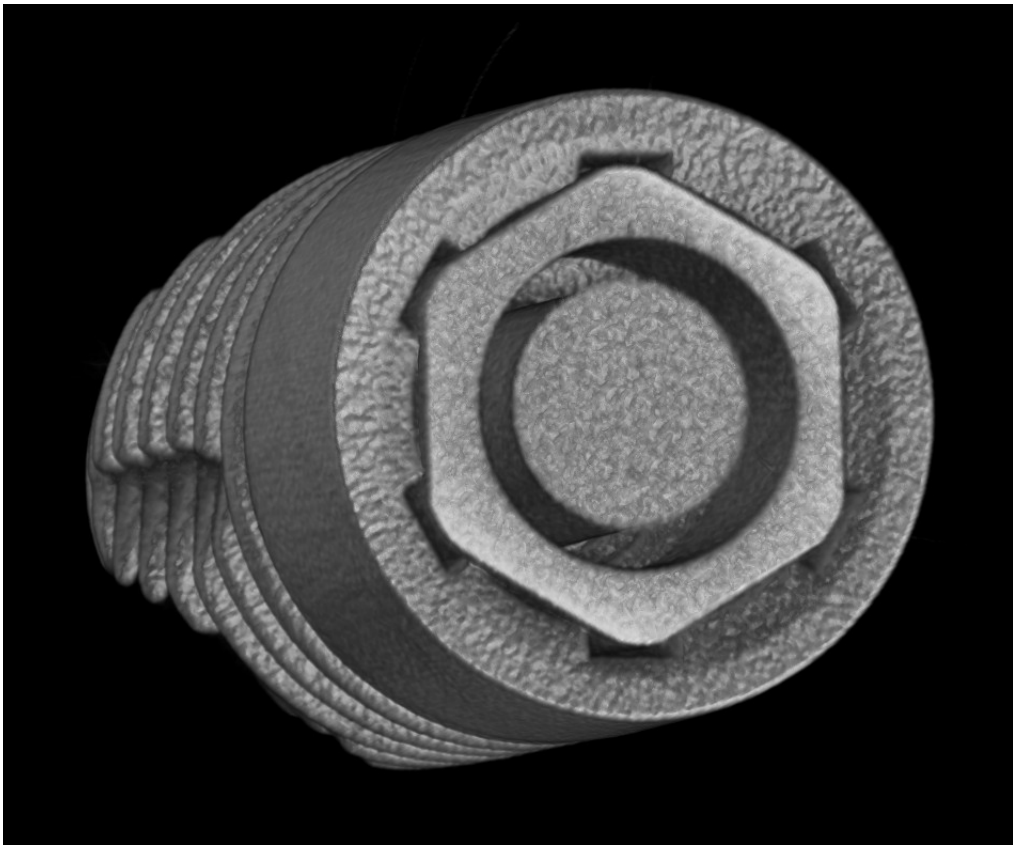


Figure 149: Specimen 6: Cross sectional transverse View 1 (high) -- Generic titanium abutment attached to Neoss ProActive implant

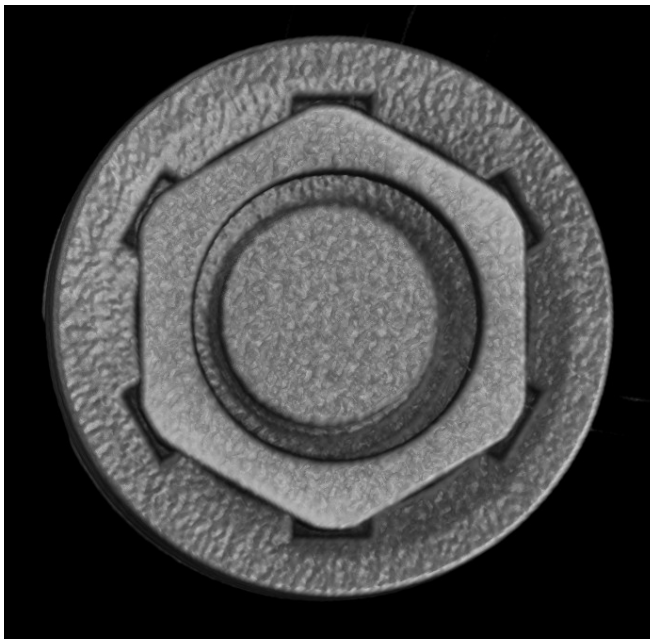


Figure 150: Specimen 6: Cross sectional View 1a (high) -- Generic titanium abutment attached to Neoss ProActive implant

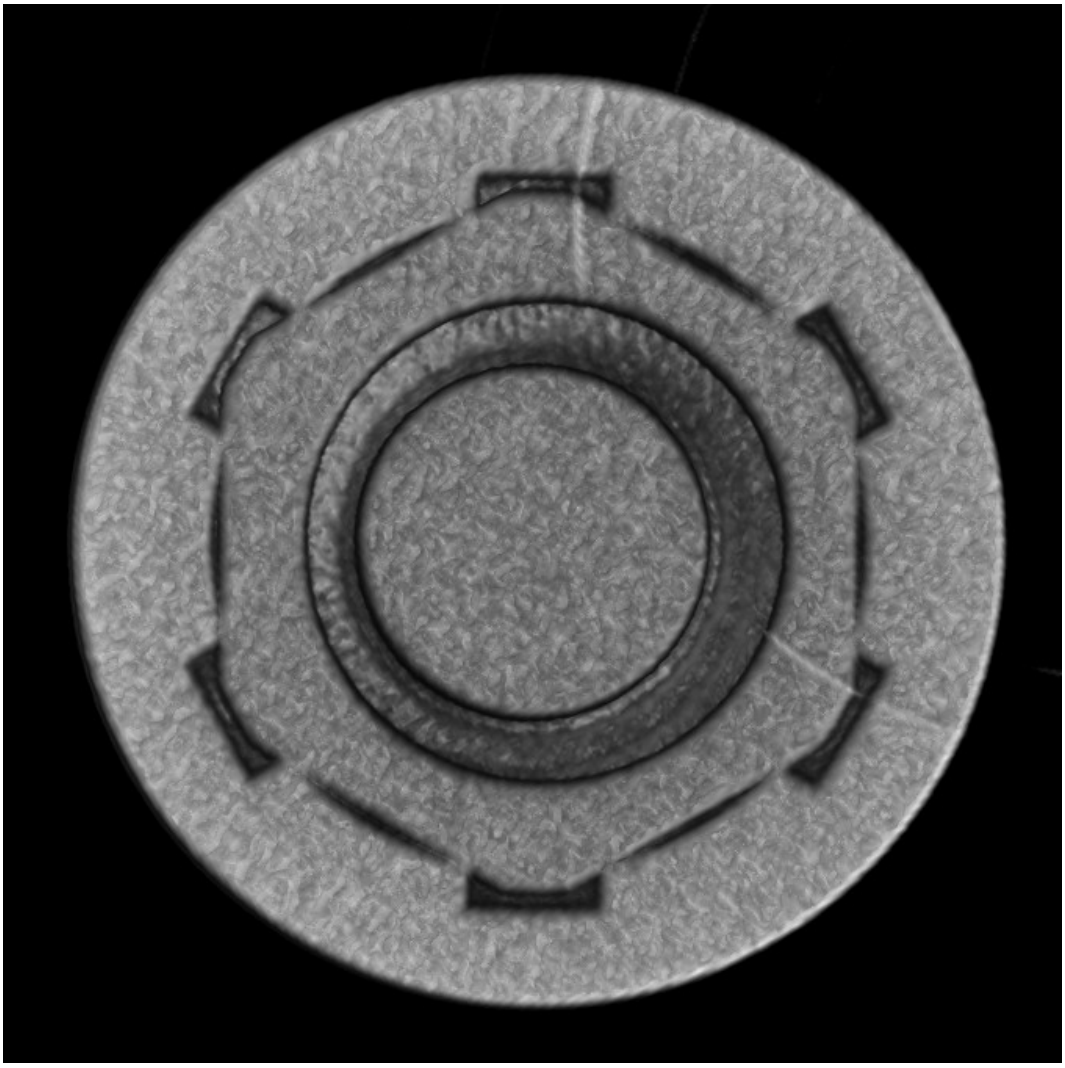


Figure 151: Specimen 6: Cross sectional View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

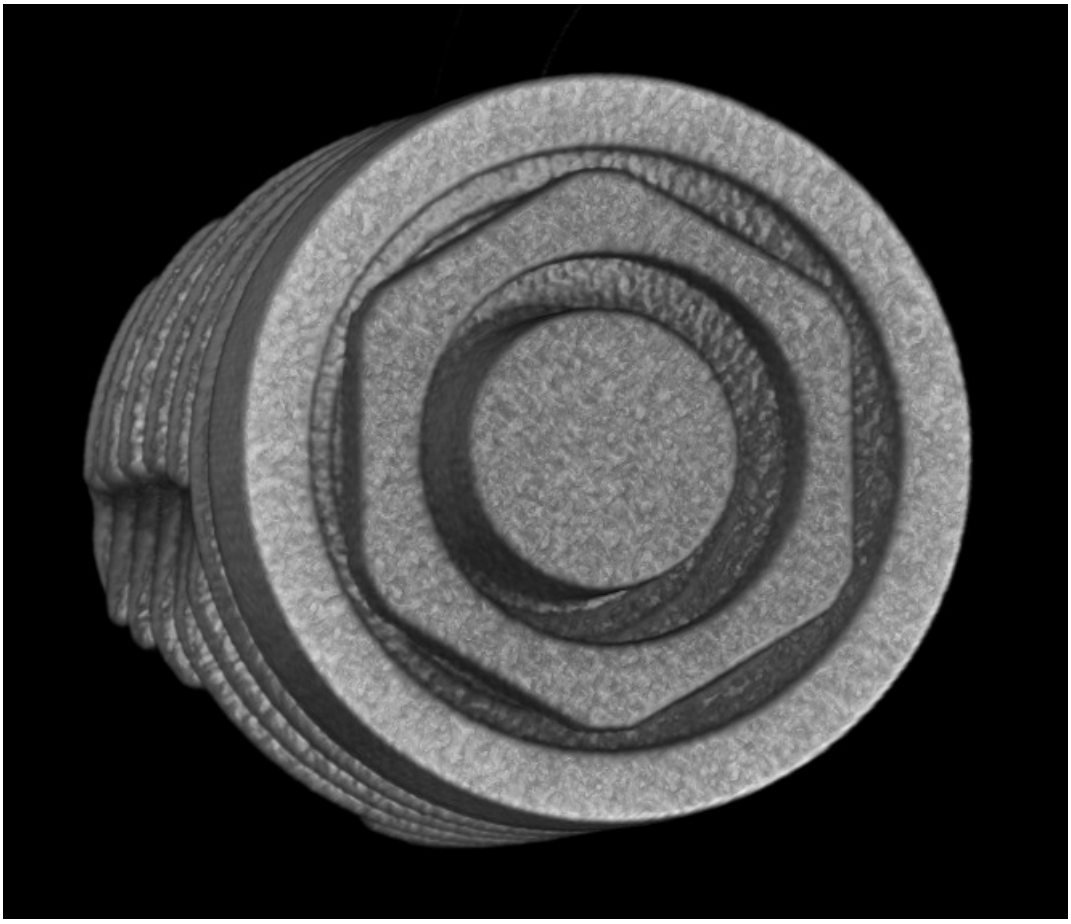


Figure 152: Specimen 6: Cross sectional View 3 (low slice) -- Generic titanium abutment attached to Neoss ProActive implant

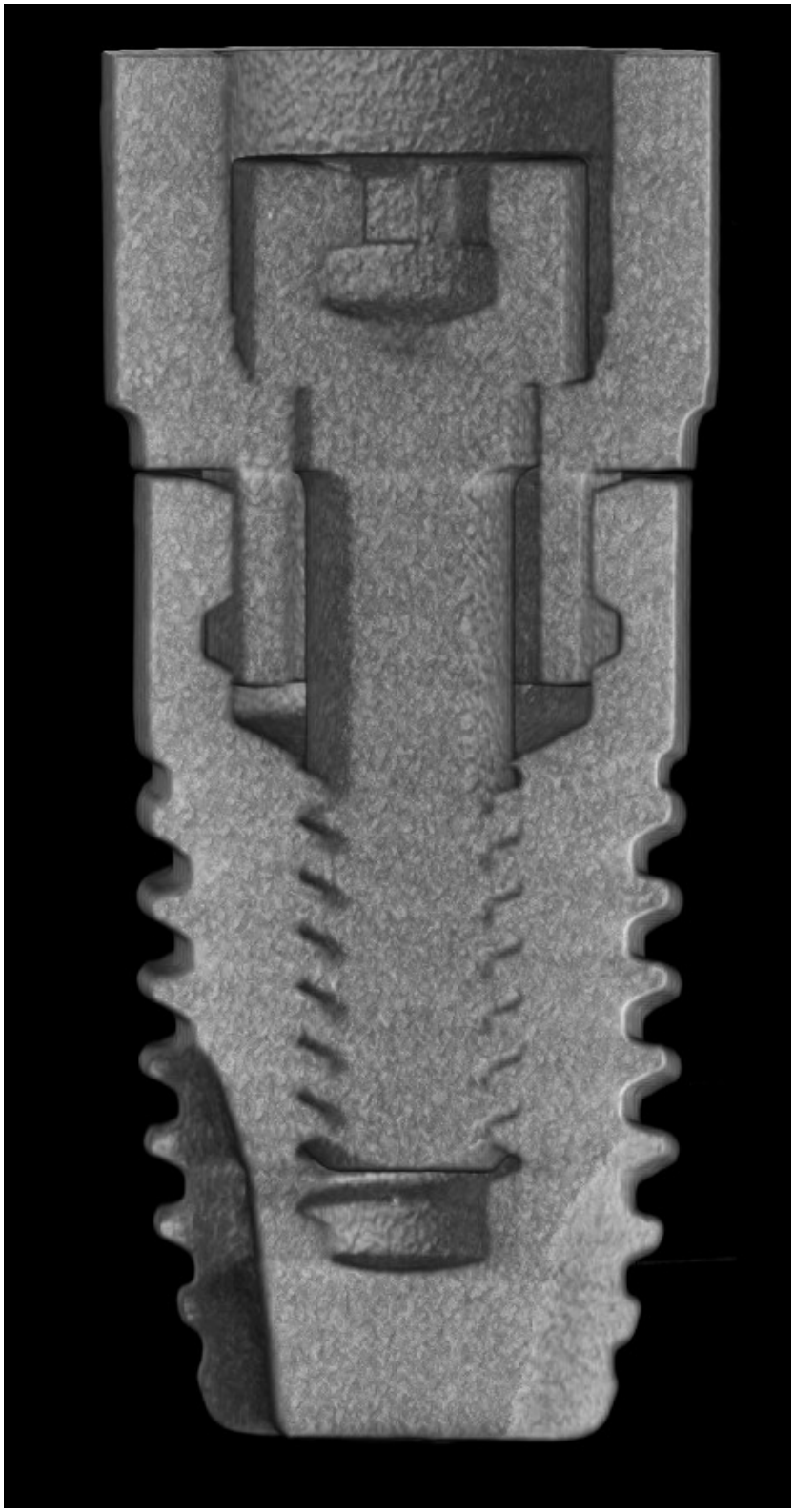


Figure 153: *Specimen 6: Coronal View 1 (anterior slice) -- Generic titanium abutment attached to Neoss ProActive implant*

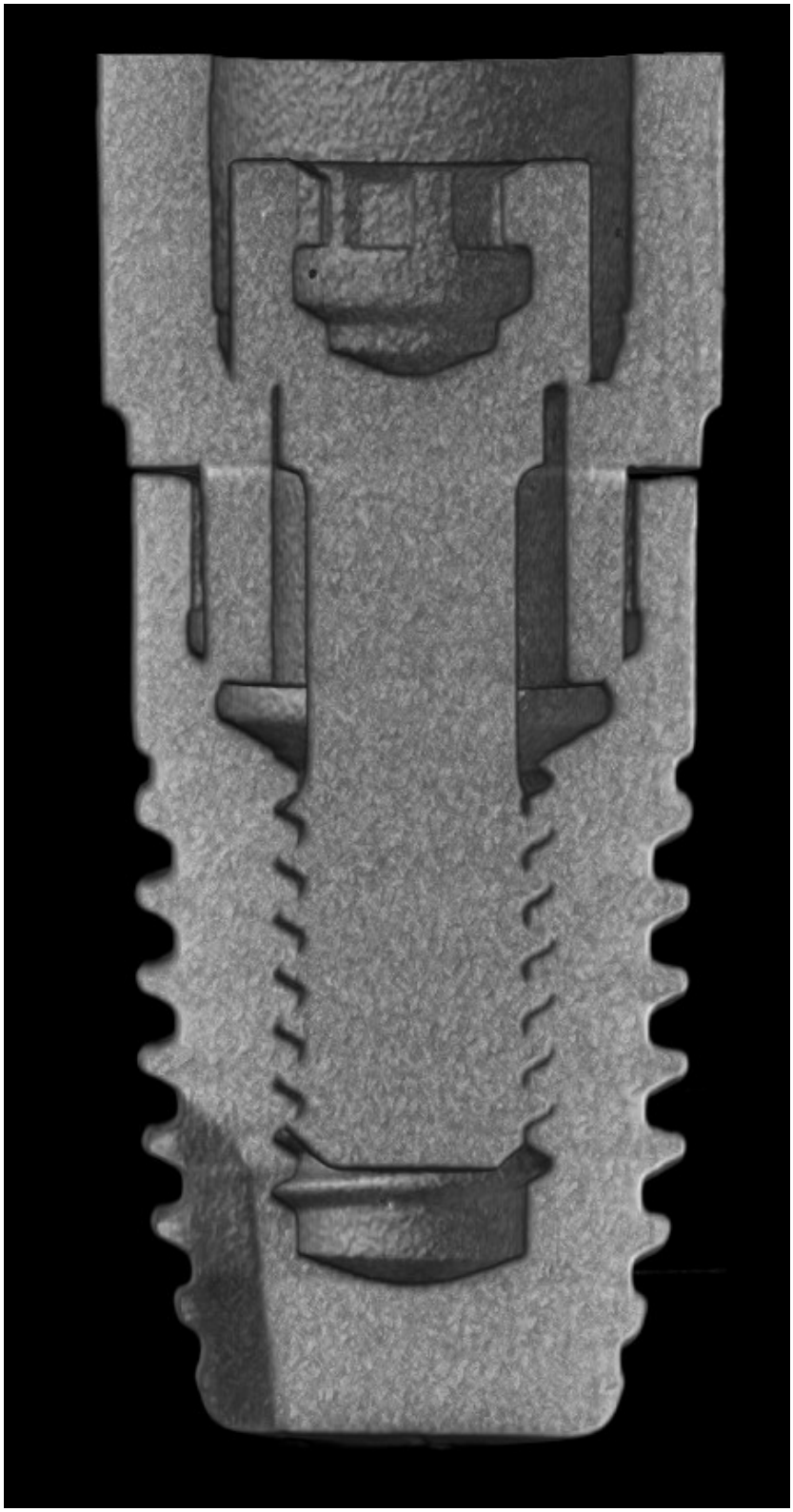


Figure 154: *Specimen 6: Coronal View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant*

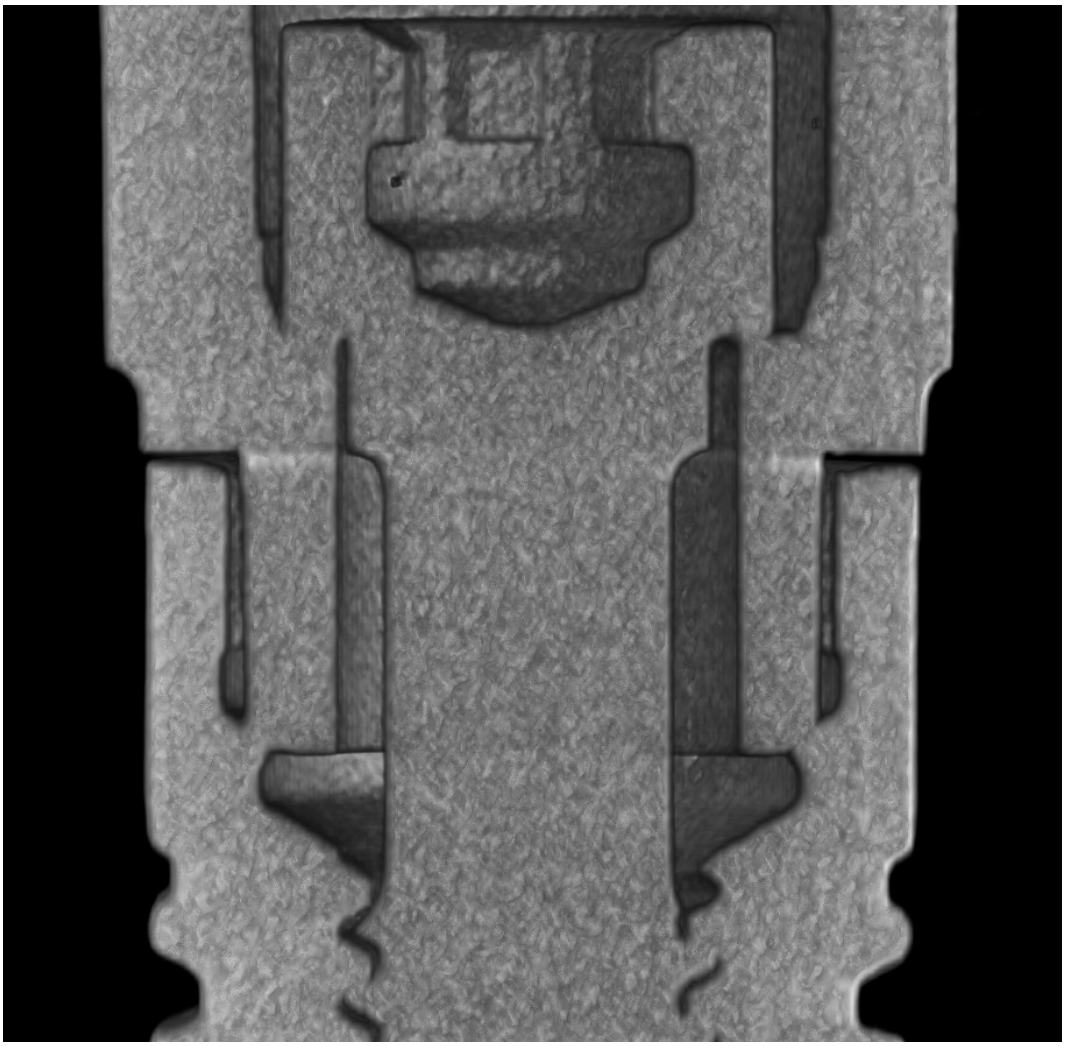


Figure 155: Specimen 6: Coronal View 2a (midpoint slice zoom) -- Generic titanium abutment attached to Neoss ProActive implant

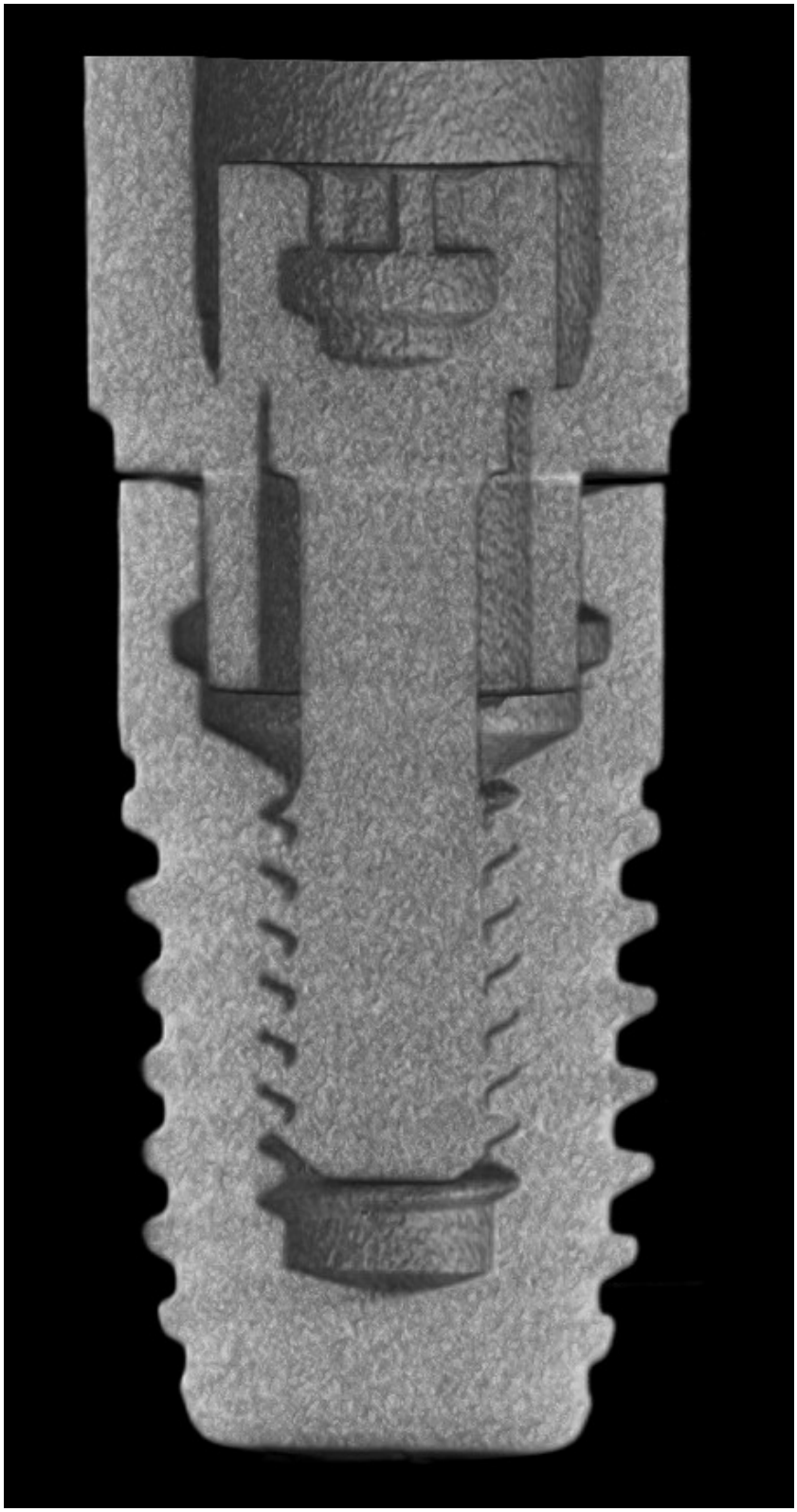


Figure 156: Specimen 6: Coronal View 3 (posterior slice) -- Generic titanium abutment attached to Neoss ProActive implant

Specimen 7

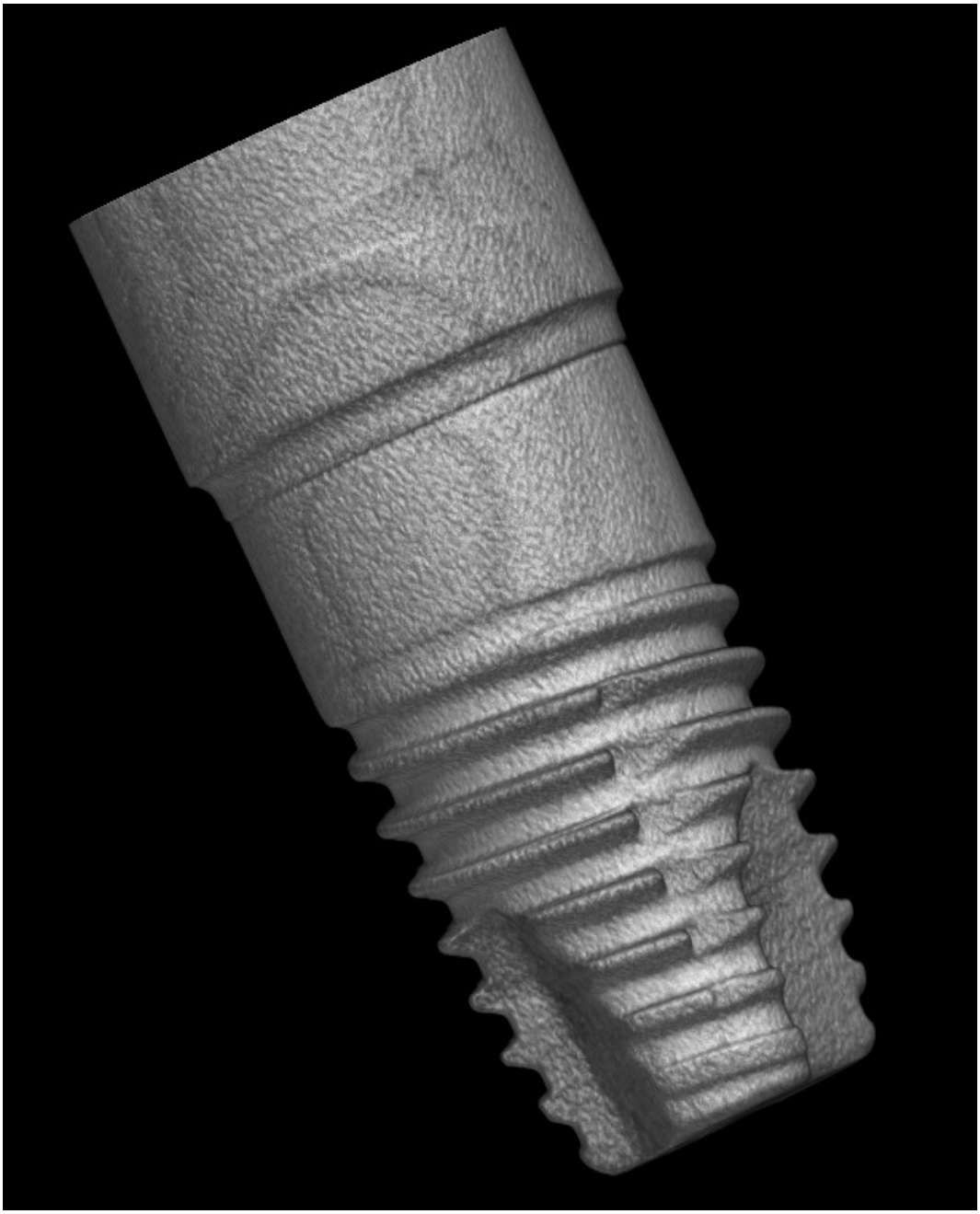


Figure 157: Specimen 7: External View 1 – Generic titanium abutment attached to Neoss ProActive implant

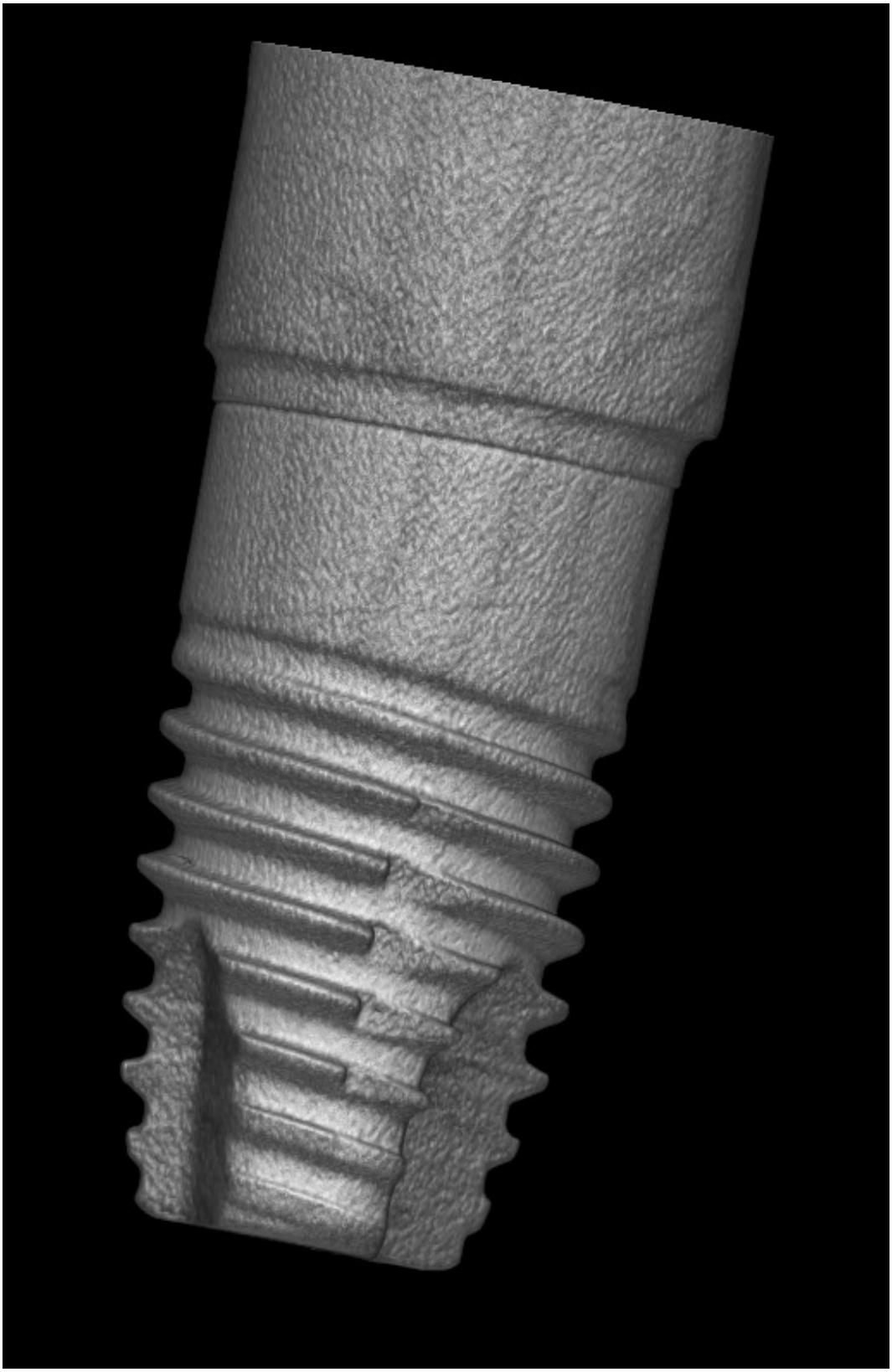


Figure 158: Specimen 7: External View 2 – Generic titanium abutment attached to Neoss ProActive implant

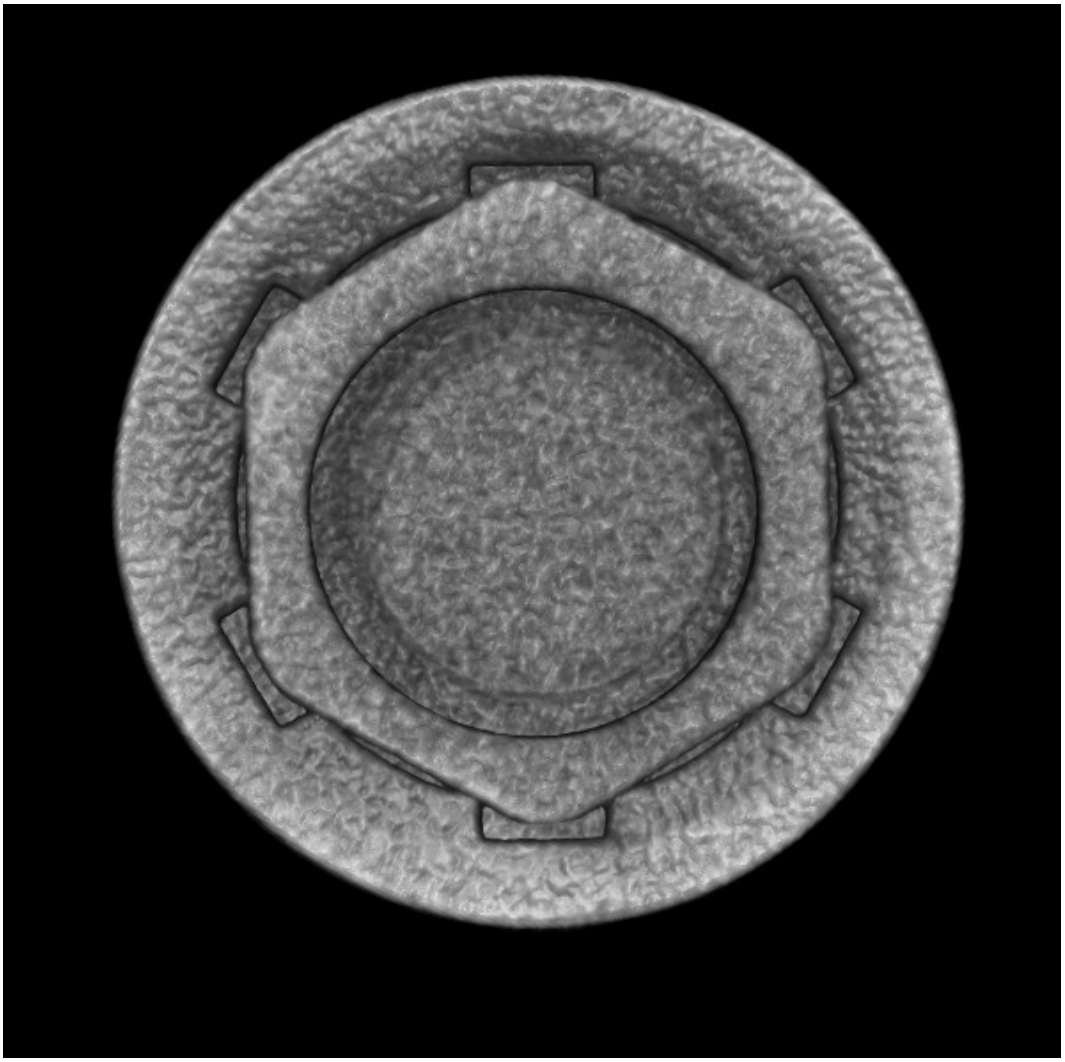


Figure 159: Specimen 7: Cross sectional transverse View 1 (high) -- Generic titanium abutment attached to Neoss ProActive implant

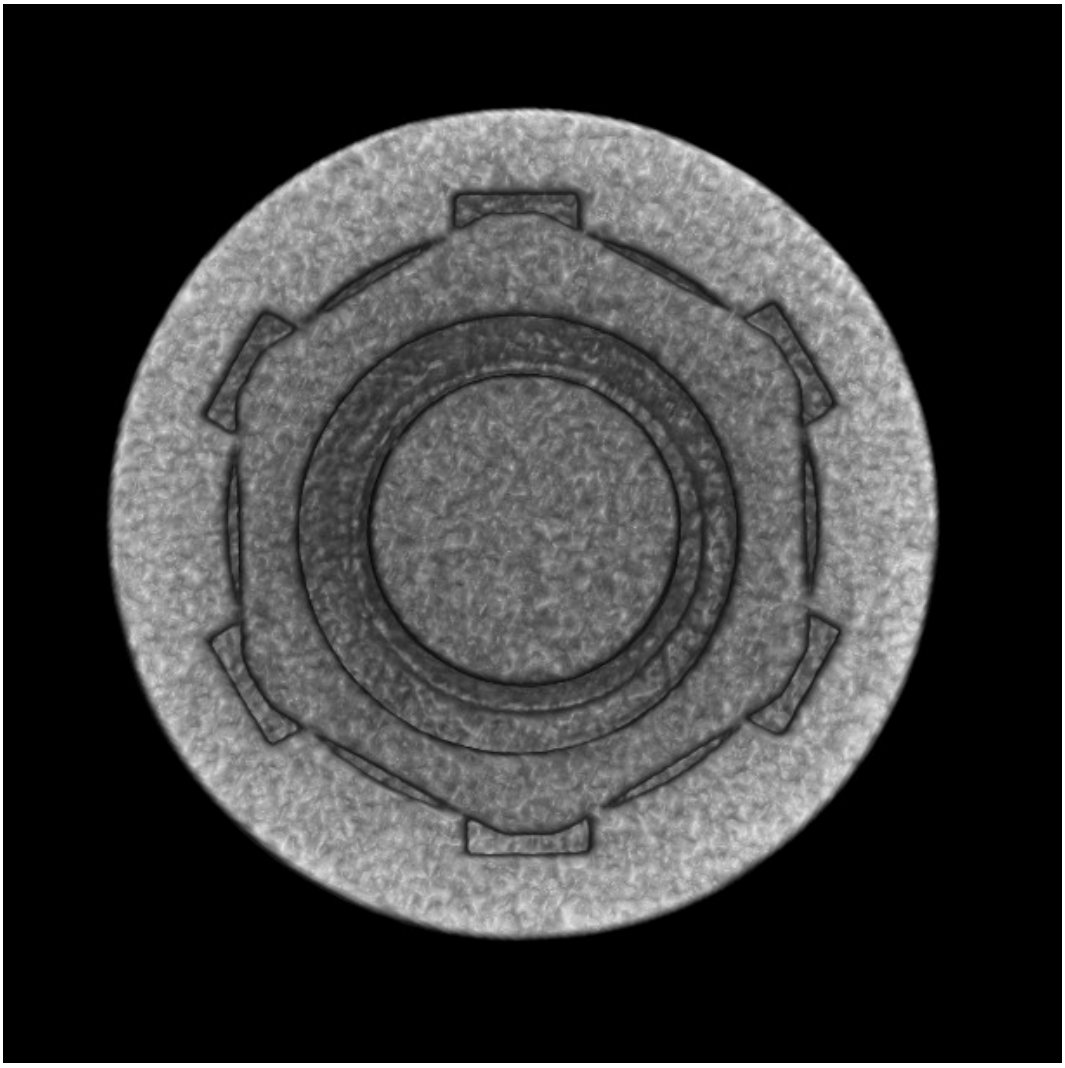


Figure 160: Specimen 7: Cross sectional transverse View 2 (midpoint) -- Generic titanium abutment attached to Neoss ProActive implant

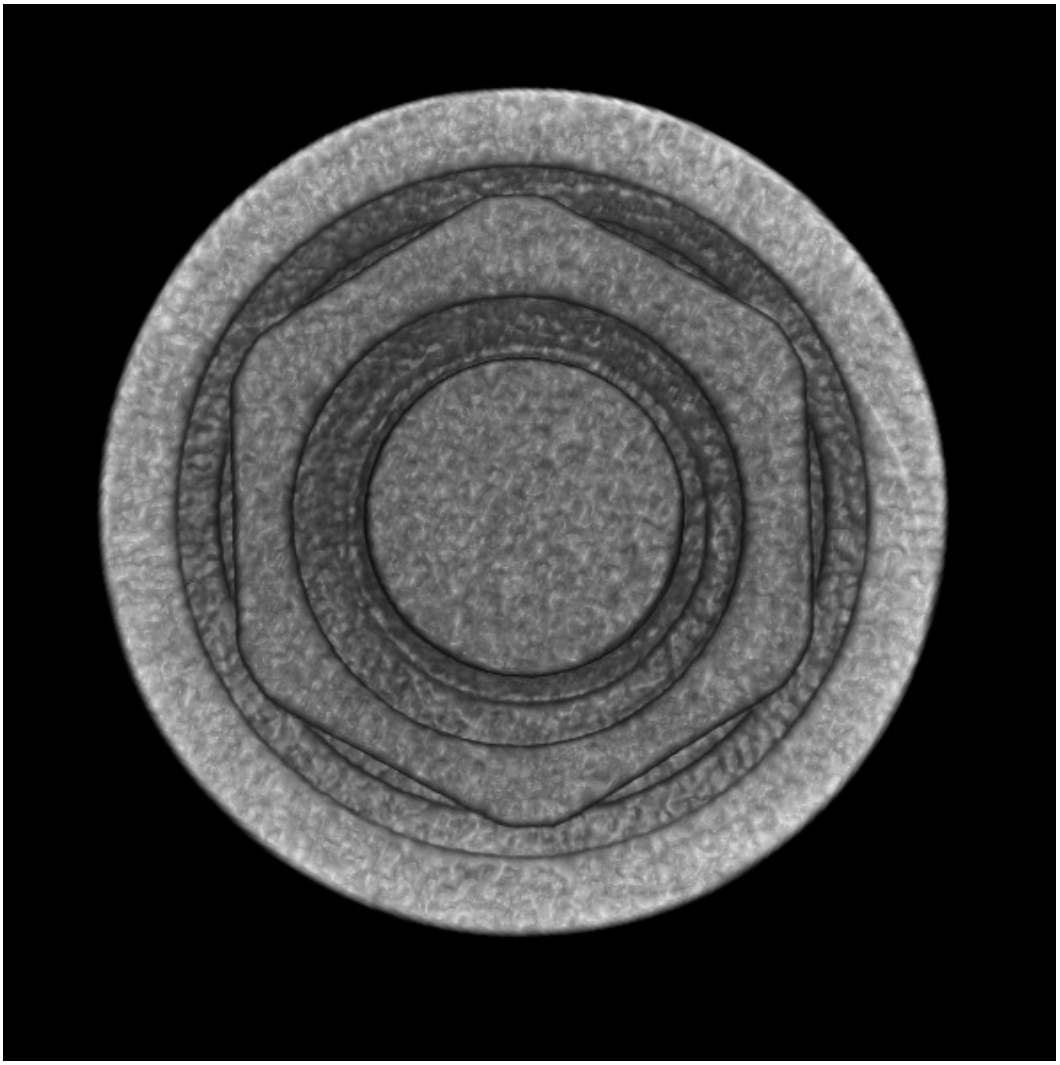


Figure 161: Specimen 7: Cross sectional transverse View 3 (low slice) -- Generic titanium abutment attached to Neoss ProActive implant

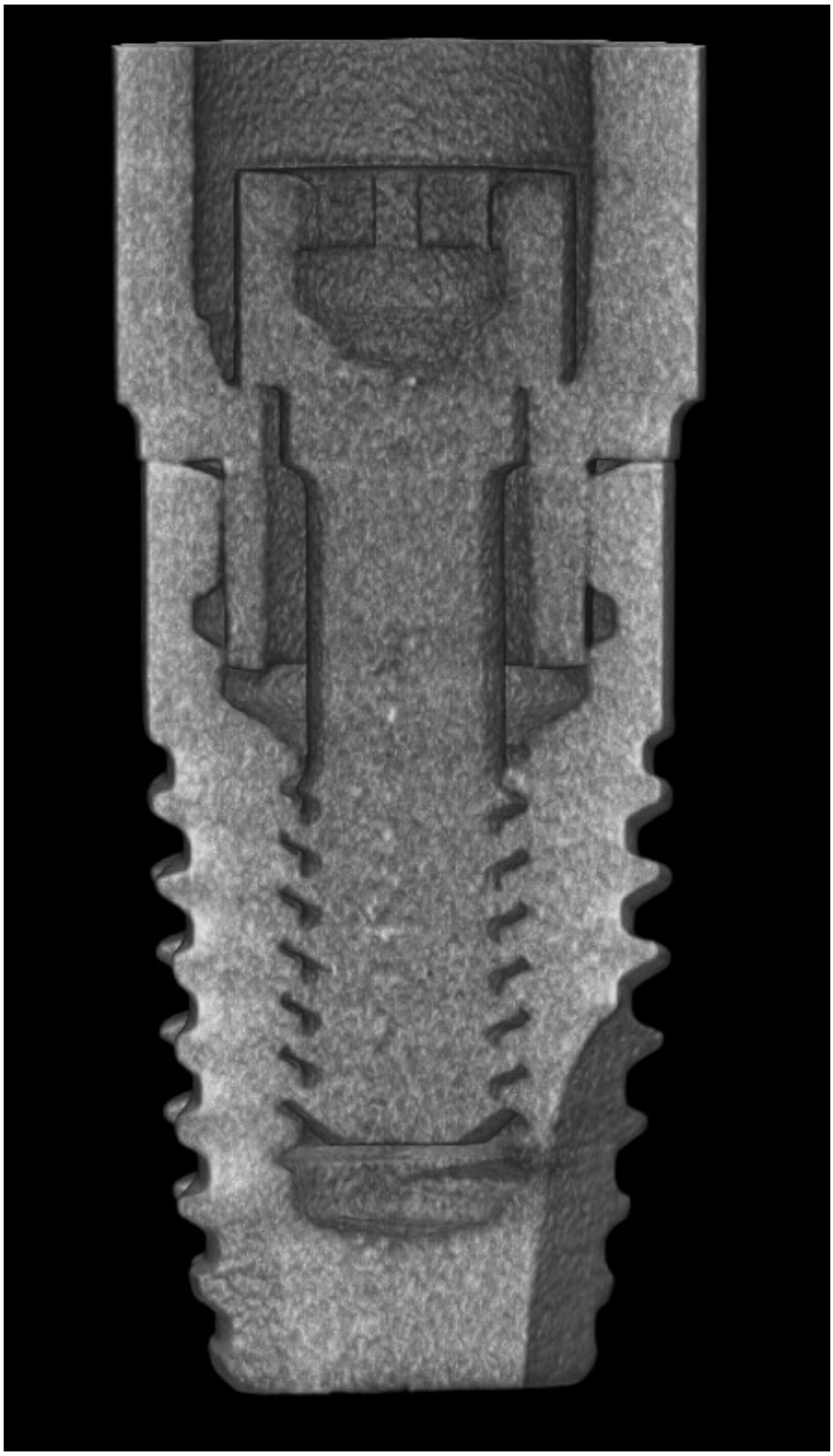


Figure 162: Specimen 7: Coronal View 1 (anterior slice) -- Generic titanium abutment attached to Neoss ProActive implant

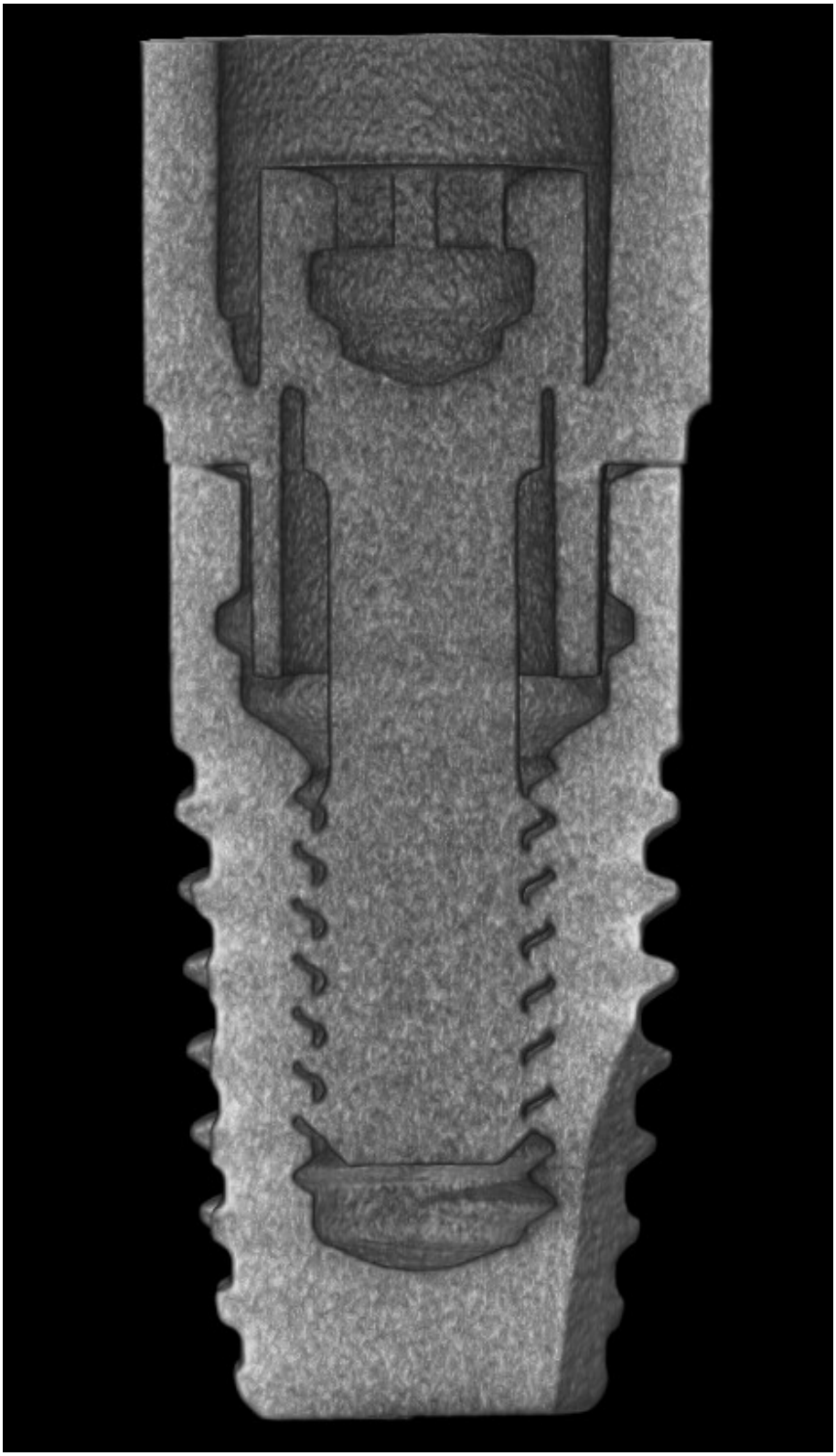


Figure 163: Specimen 7: Coronal View 2 (midpoint slice) -- Generic titanium abutment attached to Neoss ProActive implant

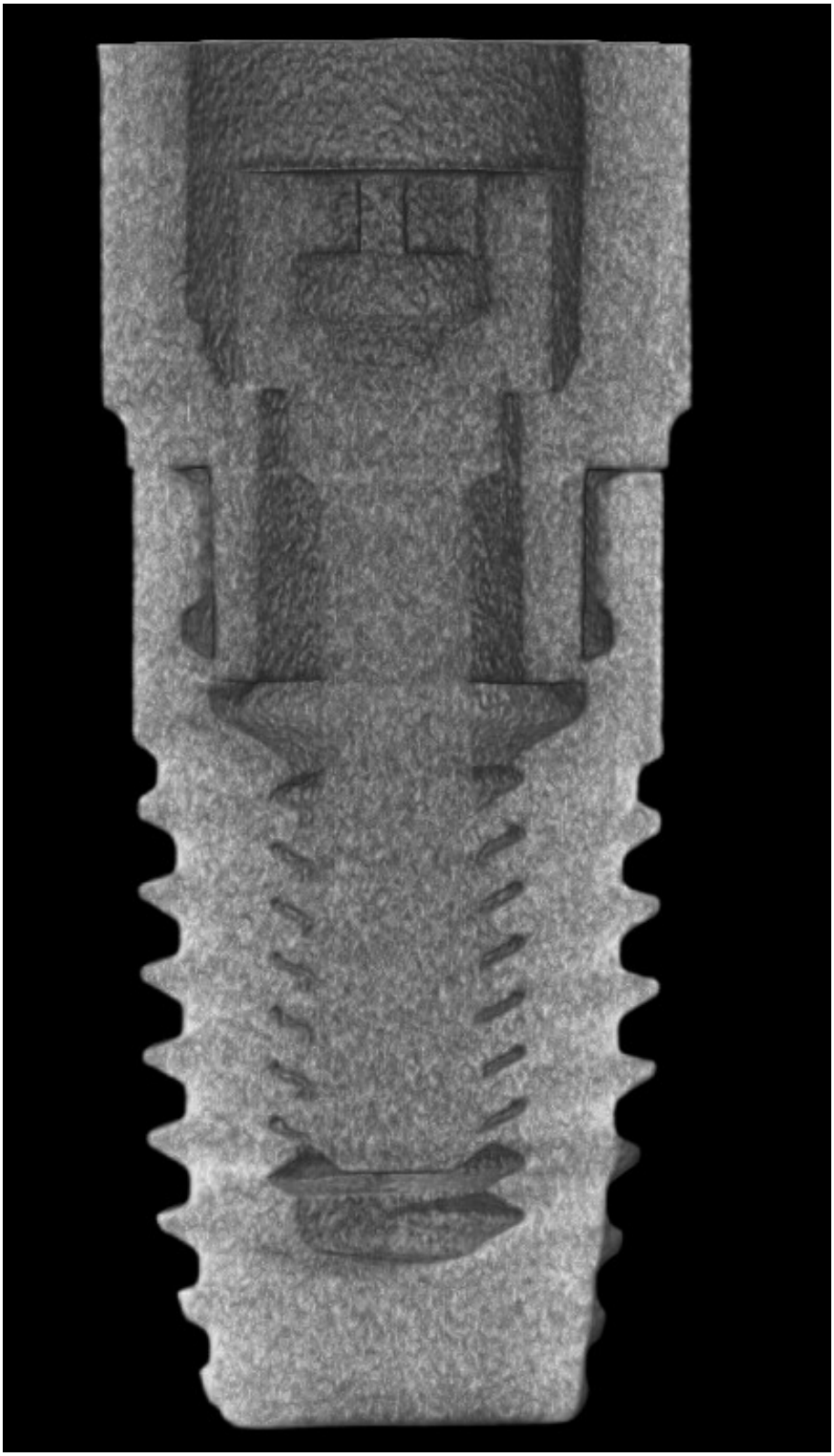


Figure 164: Specimen 7: Coronal View 3 (posterior slice) -- Generic titanium abutment attached to Neoss ProActive implant