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École doctorale Sciences, Technologies, Santé Galilée

ÉVALUATION *IN VITRO* DE LA RÉTENTION, DE LA PERTE DE RÉTENTION ET DE L'USURE DE TROIS SYSTÈMES D'ATTACHEMENTS AXIAUX UNITAIRES SUPRA-IMPLANTAIRES

***In vitro* assessment of retention, retention loss and wear of three unsplinted implant-supported attachment systems**

THÈSE DE DOCTORAT
présentée par

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Liste des abréviations

La liste ci-dessous regroupe par ordre alphabétique les abréviations utilisées dans le manuscrit. Les acronymes ou abréviations contenus dans les articles, sont explicités directement dans les publications.

CFAO : conception et fabrication assistée par ordinateur

CID : cycle d'insertion-désinsertion

DR : dispositif de rétention

PAC : prothèse amovible complète

PACIR : prothèse amovible complète complète implanto-retenue

PACM : prothèse amovible complète mandibulaire

PAPBM : prothèse amovible partielle à base métallique

PEEK : polyetheretherketone

PEKK : polyetherketoneketone

PMMA : polymethyl methacrylate

SA : système d'attachement

SAB : système d'attachement boule

SAC : système d'attachement cylindrique

Introduction générale

L'édentement, maxillaire ou mandibulaire, apparaît progressivement avec l'âge pour cause de caries, de maladies parodontales ou de traumatismes [1]**.** Les difficultés de sustentation, de rétention et de stabilisation sont particulièrement importantes à la mandibule du fait de l'étroitesse de l'arcade, de sa forte résorption et de la présence de la langue très mobile.

Les édentements partiels en extension (classes I et II de Kennedy) sont plus difficiles à restaurer du fait de la différence de dépressibilité tissulaire entre d'une part les dents entourées de leur ligament parodontal, et d'autre part l'os alvéolaire recouvert de fibromuqueuse. Cette différence est à l'origine de mouvements d'enfoncement de la selle prothétique en extension [2]**,** en particulier les mouvements de translation verticale et les mouvements de rotation verticale plus complexes à maîtriser, notamment dans les édentements de classes I et II de moyenne ou grande étendue.

Pour traiter une arcade mandibulaire totalement ou partiellement édentée, les bénéfices de l'implantologie en prothèse fixée sont aujourd'hui clairement démontrés. En cas de recours à la prothèse amovible, il existe une grande variété de modèles associant prothèses et implants selon le type d'édentement, le nombre d'implants, et la connexion entre la prothèse et les implants.

Dans les édentements partiels de classes I et II, une nouvelle approche a émergé dans la littérature ces dernières années, associant la prothèse amovible partielle à base métallique (PAPBM) à un implant posé dans la portion d'arcade édentée. L'implant peut être positionné soit très postérieure, soit proche de la dent bordant l'édentement [3,4,5,6] mais il existe peu d'études scientifiques rigoureuses sur l'association PAPBM conventionnelle et implants. Toutefois, le recours aux implants, associé à une conception spécifique du châssis métallique (forme, volume, positionnement des différents éléments constitutifs) permet aujourd'hui en clinique de traiter de façon rationnelle les problèmes d'équilibre et d'inconfort posés par ce type de prothèse à la mandibule.

En ce qui concerne la prothèse amovible complète mandibulaire (PACM), il est aujourd'hui admis qu'elle prend ancrage sur 1 à 4 implants insérés dans la zone inter-foraminale [7]. Selon le consensus de McGill établi en 2002 [8] et réactualisé en 2009 [9], la rétention sur 2 implants est considérée comme la norme. Les systèmes d'attachements (SA) supra-implantaires font donc le

lien entre l'implant et la prothèse. Ces SA autorisent différents mouvements comme le mouvement vertical d'insertion/désinsertion lors de la mise en place et du retrait de la prothèse, et le mouvement de rotation pour s'adapter à l'enfoncement de la prothèse sur ses surfaces d'appui sous l'action des forces masticatoires. De nombreux SA sont maintenant proposés aux chirurgiens-dentistes avec i) des caractéristiques géométriques diverses (boules (SAB) ou cylindriques (SAC)), et ii) et des dispositifs de rétention (DR) fabriqués dans différents matériaux (gaines en polymère ou en métal). Ces différences ont des répercussions non négligeables sur leurs comportements mécaniques au cours du temps (rétention initiale, usure, perte de rétention, besoin de maintenance).

A ce jour, il existe peu de données scientifiques permettant de soutenir l'utilisation d'un SA, sphérique ou cylindrique, plutôt qu'un autre. Les preuves sont insuffisantes pour déterminer leur efficacité relative en termes de coûts, de satisfaction ou de préférence du patient, de succès prothétique ou de maintenance (possibilités de réparation et d'adaptation, maintien de l'hygiène pour une PACM retenue sur 1 à 4 implants) [7]. La rétention initiale et la perte de rétention dans le temps, due à l'usure ou à la fracture du SA restent les critères majeurs de jugement de la satisfaction des patients et donc des praticiens souvent confrontés à des calendriers de maintenance cliniques plus ou moins serrés [10,11].

Cette thèse regroupe en trois chapitres les objectifs suivants :

- Réaliser une revue de la littérature sur les différents SA axiaux unitaires supra-implantaires de type boule ou cylindrique utilisés en PACM retenue sur 1 ou 2 implants. De façon plus spécifique, il s'agit de comparer les SAB et les SAC sur les critères suivants : rétention initiale, perte de rétention dans le temps, usure, maintenance clinique. Ces travaux ont été publiés dans l'article 1 (chapitre 1).

- Mettre au point un dispositif expérimental *in vitro* pour mesurer la rétention d'un SA en simulant une PACM retenue sur 1 implant ancré dans l'os mandibulaire. La fiabilité de ce dispositif est évaluée sur 3 SA : un SAB, le Ball System proposé par Nobel Biocare et qui dérive du Dalbo® Plus (SA le plus caractérisé dans la littérature), et deux SAC, les plus efficaces dans leur catégorie d'après la littérature : le Locator R-Tx® et le Novaloc®. Cette étude a été publiée dans l'article 2 (chapitre 2).

- Suivre l’évolution dans le temps de la perte de rétention et de l’usure des DR de ces trois SA afin de conclure sur leur pertinence clinique. Cette étude fait l’objet de l’article 3 (chapitre 3).

Ces trois chapitres sont présentés sous forme d’un résumé succint précédant l’article publié ou le brouillon. Des données complémentaires non publiées, apportant des précisions sur le protocole expérimental et les résultats sous chargement cyclique, ont été rassemblées dans le chapitre 4.

Chapitre 1 : Analyse de la littérature

Matériels et méthodes

L'article 1 présente un bref historique des SA et une revue systématique de la littérature réalisée sur PubMed/Medline conformément aux directives PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis), dressant un premier constat sur les connaissances actuelles sur la rétention initiale, la perte de rétention dans le temps, l'usure et la maintenance clinique des SA supra-implantaires utilisés en PACIR sur 1 ou 2 implants. 45 articles ont été identifiés sur un total de 1134 sélectionnés, dont 14 études cliniques et 31 études *in vitro*. Pour chaque article, l'évaluation de la qualité de l'étude a été effectuée en utilisant l'outil RoB2 (Cochrane risk-of-bias tool for randomized trials).

Résultats et Discussion

Les principaux résultats sont les suivants :

1. Rétention et usure : La force de rétention initiale du SAC est plus élevée que le SAB. La perte de rétention, essentiellement due à l'usure du DR, est responsable de la majorité des actes de maintenance du SA (activation ou changement du DR). Les pièces en polymère s'usent davantage et plus rapidement que les pièces métalliques. Ainsi, la rétention initiale des SAC est meilleure que celle des SAB mais cet avantage diminue au cours du temps avec l'usure et implique une maintenance régulière. Aucun système ne semble présenter un avantage net sur les autres.

2. Recommandations cliniques : Le choix du SA dépend des besoins spécifiques de chaque patient et de sa situation clinique : un SAB sera privilégié pour une rétention initiale faible et plus durable dans le temps (patient handicapé ou ayant des difficultés à se rendre régulièrement chez son praticien) ; un SAC pour une rétention plus élevée (parafonction linguale, bruxisme, faible surface de sustentation) nécessitant une maintenance plus régulière.

3. Variabilité des protocoles : La comparaison directe des études analysées est difficile en raison de la grande variabilité des paramètres suivants :

- Les paramètres prothétiques tels que le type de prothèse simulée, le nombre d'implants, la distance et l'angulation interimplantaire ;
- Les paramètres expérimentaux tels que l'environnement (salive artificielle, air, …) ou les conditions de chargement ;
- Les paramètres cliniques tels que la qualité osseuse, le type de prothèse sur l'arcade opposée, l'hygiène bucco-dentaire et prothétique.

Conclusion et Perspectives

Une standardisation des protocoles permettrait d'analyser de manière similaire les paramètres pertinents d'un point de vue clinique (rétention, usure, maintenance) et d'aider le clinicien à sélectionner le SA sur des critères objectifs et scientifiques.

Article 1

Les travaux relatifs à cette revue systématique sont détaillés dans l'article ci-dessous, publié en mars 2022 dans *Materials*.

materials

MDPI

Systematic Review

Evaluation of Retention, Wear, and Maintenance of Attachment Systems for Single- or Two-Implant-Retained Mandibular Overdentures: A Systematic Review

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Abstract: Attachment systems (AS) enhance retention and stability by anchoring the overdentures to implants. Since 2002, the McGill consensus statement recommends the 2-implant-retained overdentures as the standard choice for edentulous mandible (2-IRMO). Considering the large number of AS available, it remains difficult for a practitioner to make a reasoned choice. A systematic review was conducted in PubMed/Medline and carried out independently by three authors, on retention, wear, and maintenance of AS used clinically or in vitro specifically for 1- or 2-IRMO. The 45 selected studies include 14 clinical and 31 in vitro studies. The risk of bias was evaluated according to the revised Cochrane risk of bias tool for randomized trials (RoB 2). The initial retention force of the cylindrical system is higher than the ball system. The retention loss, related to the wear of the retention device, is responsible for the most common need of maintenance, requiring activation or replacement. Plastic retention devices wear out faster and more significantly than metal ones, implying a worse time behavior of cylindrical systems, but their maintenance rate is similar. Neither system appears categorically superior. Cylindrical systems provide higher initial retention than ball ones; this advantage reduces over time with wear without affecting their need for maintenance.

Keywords: ball and cylindrical attachment systems; implant-retained overdenture; retention force; wear; maintenance

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1. Introduction

Different attachment systems (AS) with varied prosthodontic designs (stud, bar, magnet, double crown) and materials (metal and polymer) are used as primary or secondary retention devices in removable mandibular overdenture, retained or stabilized on implants [1–6]. According to the McGill consensus [3,6–9], or York Consensus Statement [10], the two-implant-retained mandibular overdenture (2-IRMO) is the standard treatment for the edentulous mandible. A more cost-effective alternative consists of an overdenture stabilized by a single midline symphysis implant (1-IRMO) [3,4]. Thus, even with a limited number of implant abutments, these AS provide better retention and stability [2,6,10–12], leading to a residual ridge height preservation [13,14] and a significant increase in chewing comfort and patient satisfaction [2,10,15]. Although IRMO is more cost-effective than a conventional prosthesis, it requires significant clinical maintenance because of wear-related retention loss of its AS and clinical needs of maintenance [5,13].

All AS for IRMO are composed of one male part, the patrix—an abutment connected to the implant—and one female part, the matrix—composed of a housing included in

the intaglio surface of removable denture containing a replaceable retention device (RD) (Figure 1). When patrix and matrix are connected, retention is provided by friction between these parts whose behavior depends on the design and the constitutive materials of these components. In IRMO, to compensate for prosthesis depression on soft tissues, the resilient junction has been standardized with a calibrated space between the matrix and patrix to reduce the stresses on the rigid implants. The AS can be classified into two categories based of their abutment, which is either ball or cylindrical.

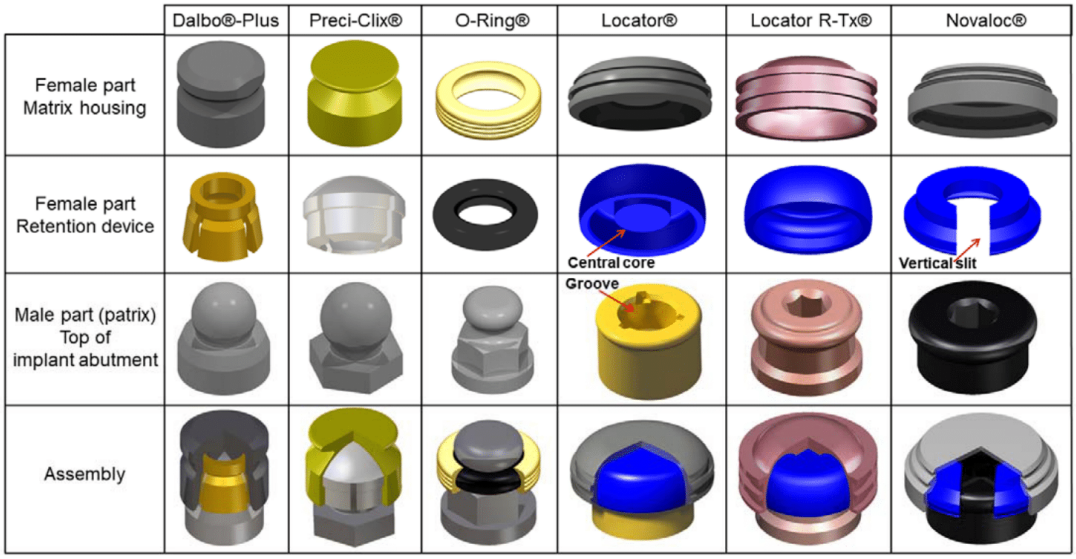


Figure 1. Design of some ball attachment systems (Dalbo®-Plus, Preci-Clix®, O-Ring®) and cylindrical attachment systems (Locator®, Locator R-Tx®, Novaloc®).

1.1. Ball Attachment Systems

The ball anchor was first proposed on dental abutments and then gradually adapted on implant supports. The most commonly used ball attachment system (BAS), Dalbo® Plus (Cendres et Métaux SA, Biel-Bienne, Switzerland) [2], shows a satisfactory stable retention force overtime. However, its volume might limit clinical indications [16], even if it is available in different sizes to adapt to the vertical and horizontal prosthetic space. The most common patrix consists of a titanium alloy 2.25 mm diameter ball [1]. In contrast, the matrix is a titanium alloy or stainless steel case with a metallic or plastic retention device (RD) [2,5,13,16].

BAS show different types of RD such as the gold alloy lamellae or strips (Dalbo® Plus or Dal-ro® (Biomet 3i, Palm Beach Garden, FL, USA) [5,8] that need to be activated using a specific screwdriver and replaced after wear or retention loss and other systems that are nonactivable but replaceable such as the stainless steel spring rings Tima® (Unor/Kaladent AG, Zurich, Switzerland) and TG-O-Ring® (Cendres et Métaux SA, Biel-Bienne, Switzerland) [5,8], the rubber rings OP-Anchor® (Inoue Attachments Co., Tokyo, Japan), O-Ring® (Biohorizons, Birmingham, AL, USA) and Steri-Oss® (Steri-Oss/Nobel Biocare, Zurich, Switzerland) [7–9], or the colored plastic RD (Southern® (Southern Implants, Irene, South Africa), Ecco® (Unor/Kaladent AG, Zurich, Switzerland)), Pro-Snap® (Metalor Dental/Cendres et Métaux SA, Biel-Bienne, Switzerland)) and Preci Clix® (Ceka Preci-Line/Alphadent, Waregem, Belgium)) [5,8] (Figure 1). In this AS, retention is ensured by friction between the RD and the patrix, mainly at the ball's equator [17].

The manufacturers' retention force ranges between 2 and 15 N depending on the chosen BAS. Although the initial retention is essential to immediately obtain the expected outcome for the patient, its stability in time is even more needed to avoid time-consuming maintenance and patient discomfort. The RD can be changed to retrieve its initial retention values in case of excessive wear and retention loss. BAS can function when implants are parallel or not. Indeed, they have been designed to accommodate changes in implant angulation up to 12, 15, 20, or 30 degrees [10,16,18,19]. The matrix components in the denture must remain parallel to the vertical path of prosthetic insertion [18].

BAS are the most widely used AS because they are easy to handle clinically, are relatively economical, and have a lower technique sensitivity [1,5,6].

1.2. Cylindrical Attachment Systems

Cylindrical attachment systems (CAS) were developed more recently to allow new AS clinical indications, especially in reduced prosthetic spaces, thanks to their smaller size and improved retention [2,6,20]. Developed in 1971, the first CAS was the Zest® (Zest Anchors, Escondido, CA, USA) which evolved in ZAAG® (Zest Anchors, Escondido, CA, USA). Nowadays, the Locator® (Zest Anchors, Escondido, CA, USA) has become the most popular CAS with the lowest profile height, an improved retention force and, a design combining the best features of BAS, ZAAG®, and ERA® (Sterngold Dental, LLC, Attleboro, MA, USA) [20–24]. When implant connections are compatible, CAS are preferred in situations of low prosthetic heights with a 2.5 mm AS [20,25–27]. However, they have a larger cross-section to maintain satisfying strength with a diameter of 4.1 mm [26].

For most CAS, the manufacturer considers (i) the cylindrical abutment as the « matrix » because of the groove in its center that allows a perfect fit of the RD acting as a push button, and (ii) the RD with its case as the patrix. For a better understanding and comparison of all AS, in this review, the names were standardized by calling the abutment the patrix, and the RD with its case included in the prosthesis the matrix (Figure 1). The Locator® patrix consists of a yellow wear-resistant nitride-coated titanium cylindrical implant abutment featuring internal and external undercuts. The matrix consists of a cylindrical stainless steel case embedded in the denture basal surface and a polyethylene RD, which will ensure a resilient connection between the denture and the implant [7,15,25], with a vertical tolerance of 1.2 mm and a possible angulation of 8 degrees in all directions [7]. As for the ERA system (White/extra-low, Orange/low, Blue/medium, Grey/heavy, Yellow/high, Red/very high), the Locator® RD are identified by color codes according to the required retention force and the angulation between implants [2]. The manufacturer claims that the retention force in this system ranges between 6.67 and 22.2 N. With standard RD (Blue/extralight, Pink/light, White/high), a difference of 10 degrees can be tolerated between the insertion axis of the RD and the central axis of the corresponding abutment. For interimplant angulations between 20 and 40 degrees, the manufacturer recommends extended RD (Red/extralight, Orange/light, Green/high).

Similar to BAS, once Locator® patrix and matrix are interlocked, retention is ensured by friction between different surfaces [2,11]: (i) between abutment's external surface and RD's internal peripheral surface and (ii), optionally for standard RD, between the groove on top of the abutment and the RD's internal central core. When the abutments are identically aligned parallel to the insertion path, retention is achieved uniformly from all the undercuts. However, in the case of angulation between them, friction will occur preferentially on the side presenting larger undercuts [25].

Since the ERA® and the Locator®, other CAS have emerged over the past ten years. All use the same design principle: a titanium alloy implant abutment—with a specific coating surface—and interchangeable color-coded color RD—included in a case embedded in the denture basal surface. New designs are proposed to improve initial retention and wear resistance. Among these new AS, the Locator R-Tx® (Zest Anchors, Escondido, CA, USA) shows an abutment with a pink wear-resistant titanium-carbon nitride coated surface, new undercut features, and four color RD (Grey/extralight, Blue/light,

Pink/medium, White/high) without internal core and has been recommended for an interimplant angulation up to 60 degrees. For the Novaloc® (Valoc, Möhlin, Switzerland), RD are made in polyetheretherketone (PEEK) to improve wear resistance and are inserted in titanium or PEEK cases. The system has six-color RD (Red/2.94 N, White/7.35 N, Yellow/11.77 N, Green/16.18 N, Blue/20.60 N, Black/25.01 N). The CM Loc® (Cendres & Métaux SA, Biel-Bienne, Switzerland) was introduced to compensate interimplant angles up to 40 degrees and have both PEEK and precious alloy cases with four replaceable PEEK RD (Green/5.88 N, Red/11.77 N, Green/17.65 N, Blue/23.54 N). One clinical trial has evaluated the performance of CAS based on PEEK RD compared to the nylon RD of the Locator® system [28], and three in vitro studies showed promising results regarding the long-term retention of PEEK RD [27,29,30].

Objectives

Considering the wide choice of marketed AS for IRMO, it remains difficult for a dental practitioner to make an appropriate clinical selection based on objective and scientific criteria. Manufacturers only provide partial data on their AS and rarely explain their testing conditions. In the literature, comparing the different studies is difficult because of the variability in their protocols and presented results. There is still no scientific data to support using one attachment system over another for the edentulous mandible [1,9,19]. Most AS are marketed without scientific and independent evaluation. This review compares the most common BAS and CAS used for 1- or 2-IRMO by assessing different criteria—initial retention and prosthodontic maintenance related to wear and retention loss—to establish the advantages and drawbacks of each system to assist the practitioner in making reasoned clinical choices.

2. Materials and Methods

2.1. Protocol

This systematic review (SR) was conducted following the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines. The protocol was registered in PROSPERO (International Prospective Register of Systematic Reviews), at the UK's National Institute for Health Research (NHS), University of York, Centre for Reviews and Dissemination, under the number: CRD42021265595. The PICO model for clinical questions was applied to structure the research question "Do Ball and Cylindrical attachment systems behave differently over time?"

1. Participants/population: Patients with completely edentulous mandibular arch mainly opposed to edentulous maxillary arch (or partial removable denture, or fixed denture, or natural teeth).
2. Intervention/exposure: 1- or 2-implant-retained mandibular overdenture using ball attachment systems (BAS) or cylindrical attachment systems (CAS) only.
3. Comparator/control: Comparison between CAS and BAS and, secondarily, their subgroups.
4. Outcomes: Initial retention, retention after clinical use, retention loss, wear, and maintenance.

2.2. Search Strategy for the Identification of the Studies

An electronic search on PubMed/Medline was carried out on 8 September 2021 using different keywords: "Denture Precision Attachment"[Mesh], "implant attachment*" OR "overdenture attachment*" OR "attachment system*" OR "stud attachment*" OR "resilient attachment*" OR "spherical attachment*" OR "ball attachment*" OR "cylindrical attachment*" OR "locator attachment*", maintenance OR complication* OR prosthodontic* OR prosthetic* OR prosthes* OR retention OR wear, "implant stabilized overdenture*" OR "implant retained overdenture*" OR "implant supported overdenture*". The search included language (English) and publication status restrictions (Abstract) with date limitation (1996–2021). In addition, a manual screening was carried out among the references of

selected articles to gather further relevant papers. Three review authors (R.W., A.B., and C.G.) assessed studies independently for eligibility by initially screening successively titles and abstracts (Figure 2). Then, the full-text articles were retrieved for further assessment when studies met the inclusion criteria. Studies that had insufficient data were excluded. Any disagreements were resolved by discussion between the two authors.

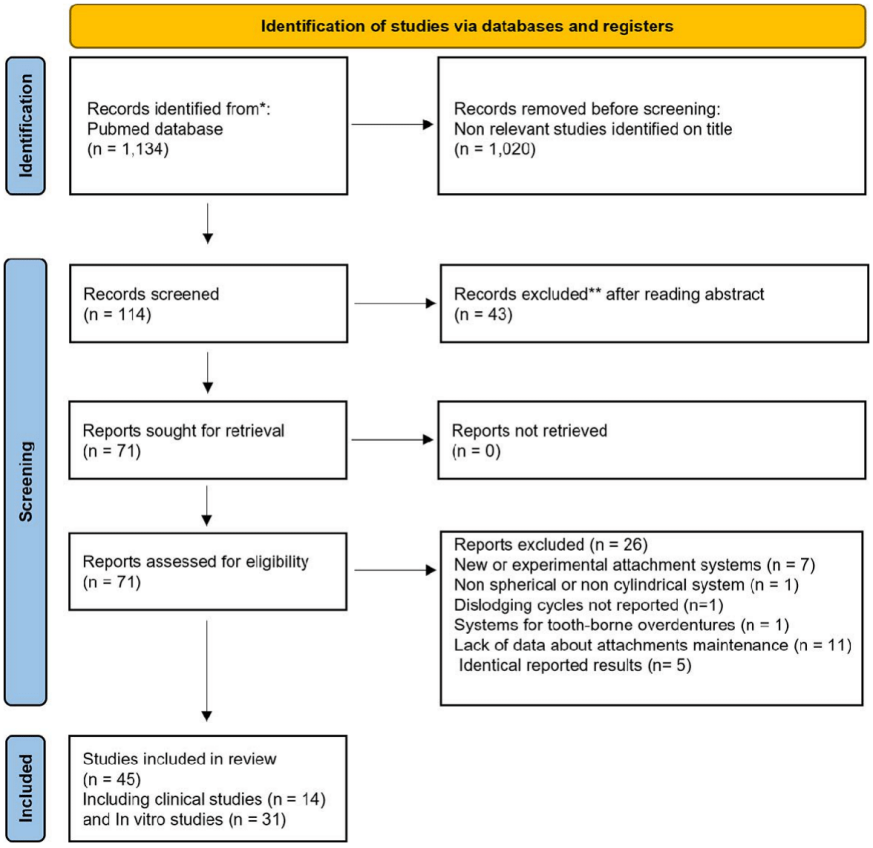


Figure 2. Search method for identification of studies using PRISMA guidelines for systematic reviews.

2.3. Eligibility Criteria

Different inclusion criteria have been used:

(i) in vitro studies reporting on initial retention, retention loss, and wear of real or simulated 1- or 2-IRMO using stud-shaped BAS or CAS,
(ii) clinical studies (i.e., prospective, retrospective, randomized controlled trials including cross-over trials) reporting on maintenance of AS (retention loss, wear) in 1 or 2-IRMO regardless of follow-up time.

The exclusion criteria were:

(i) maxillary overdenture,
(ii) partial dentures,
(iii) fixed overdentures,
(iv) overdentures on remaining natural teeth or roots,

(v) more than two implants,
(vi) implant splinting,
(vii) other AS (bars-clips, magnets, telescopic double crowns),
(viii) anecdotal BAS and CAS.

Comparative studies were rejected if only one type of BAS or CAS was used versus other AS. Case reports, reviews, and short communications were rejected.

2.4. Outcome Measures

The primary outcome measures concerned:

(i) the initial retention and its evolution over time of clinical use (Newton (N), loss of retention (%)), in correlation with the observed wear patterns (scanning electron microscopy with qualitative description) and the dimensional changes (µm) of AS components,
(ii) the maintenance follow-up (frequencies: months/years), and maintenance procedure of AS (activation/replacement).

The secondary outcomes were to report:

(i) the effects of denture cleansing solutions on the retention and wear of AS,
(ii) the overdenture maintenance (i.e., reline/rebase of denture, fracture repair or occlusal adjustment, denture replacement),
(iii) the interimplant distance (mm) or angulation (°) and their impact on primary outcomes.

2.5. Data Extraction and Analysis

For eligible studies, data were extracted and collected in an Excel spreadsheet by one review author (R.W.) and checked by two others (A.B., C.G.) independently. In case of disagreement, a consensus was obtained with discussion between the authors. Finally, 45 articles have been identified out of a total of 1134 selected among which 14 clinical and 31 in vitro studies.

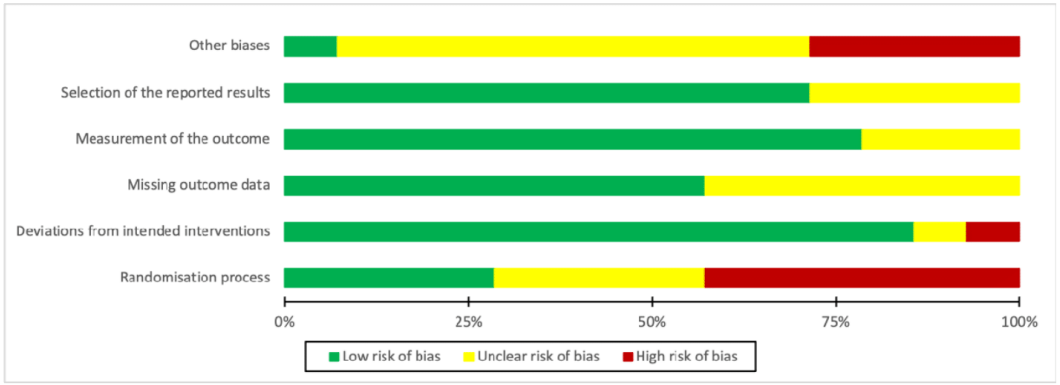
2.6. Study Quality Assessment

The quality assessment of each clinical and in vitro study, based and adjusted from the revised Cochrane risk of bias tool for randomized trials (RoB 2) [31] was independently evaluated by two review authors (R.W., A.B. for in vitro studies, and R.W., C.G., for clinical ones). Differences were resolved after team discussion.

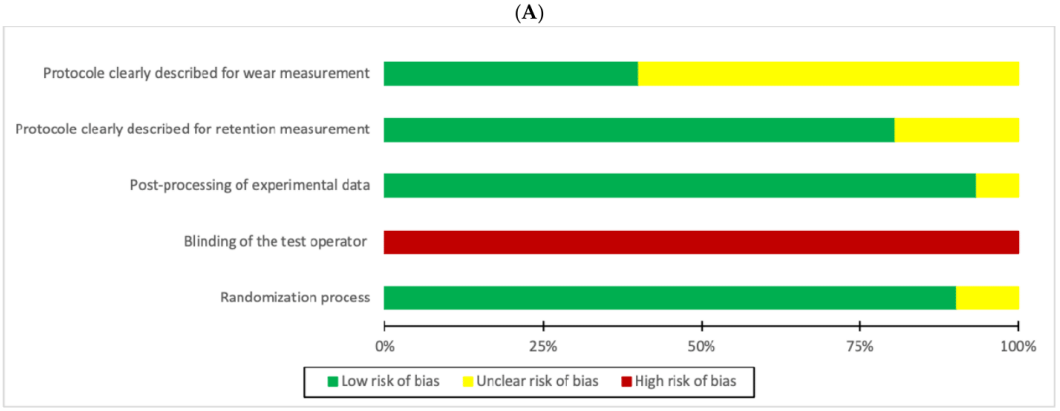
For the clinical studies, the risk of bias (RoB) was assessed by the following items: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, selection of the reported result, and other biases such as the presence of a control group, description of inclusion criteria, the status of the maxillary arch (complete edentulous and overdenture), years of follow up ($\leq$1, low; $\leq$2, middle; $\geq$3, high), follow-up planning. For other biases, the study received a 'yes' if at least 4 parameters were respected over 5, a 'middle' if only 3 parameters were respected and a 'no' otherwise. RoB 2 criteria were adapted for in vitro studies, assessed by the following items: randomization process, blinding of the test operator, post-processing of experimental data (sample size and statistical analysis), and detailed protocol for retention and wear measurements.

Each item was evaluated following RoB 2 recommendations. Finally, to assess the overall RoB, a study with at least one 'no' was classified as 'high RoB', a study with 'unclear' or 'middle' for one or more items was classified as 'unclear RoB' (except in both cases for other biases for clinical studies and blinding of the test operator for in vitro studies). A study with 'yes' in all domains was classified as 'low RoB'.

Among the 45 selected studies, 25 studies showed a low RoB and 13 moderate RoB. Only 7 clinical studies exhibited a high RoB, primarily due to their lousy score for randomization. In vitro studies were poorly scored for the blinding of test operators, but it did not impact their overall RoB (Figures 3 and 4).

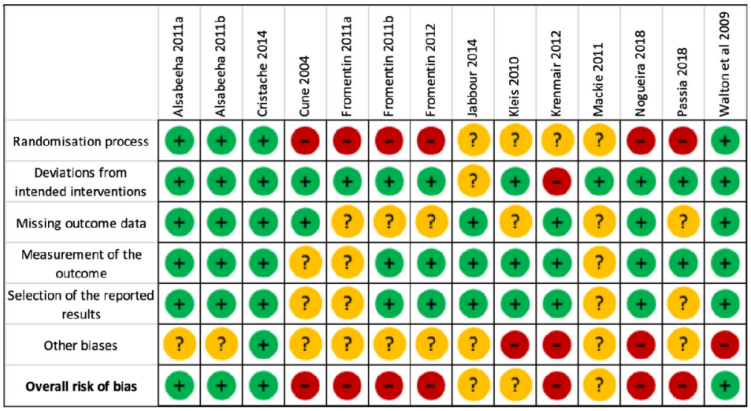


(**A**)



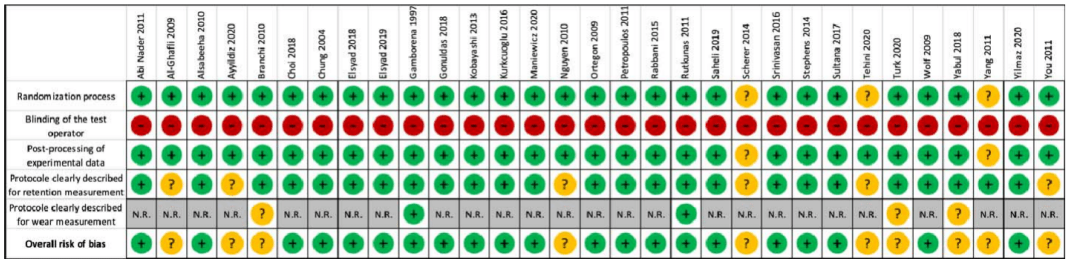
(**B**)

Figure 3. Risk of bias graph: author's assessment of each risk of bias item in proportions for all clinical (**A**) and in vitro studies (**B**).



(**A**)

Figure 4. *Cont.*



(**B**)

Figure 4. Risk of bias summary: authors' assessment of each risk of bias item for each included clinical (**A**) and in vitro study (**B**).

3. Results and Discussion

According to the aim of this SR, the results are presented in four parts: (i) the initial retention of BAS and CAS, (ii) the retention loss and wear of AS correlated to the prosthodontic maintenance; the influence of implant parameters (iii) and experimental conditions (iv) on the retention, wear, and maintenance. Finally, paragraph (v) exposes the limitations of our study and, in particular, the difficulty of comparing studies directly because of the variability in their protocols and reported results.

3.1. Initial Retention of BAS and CAS

Retention is defined as the maximum force developed until dislodgement of the denture from its mucosal and/or implants bearing surfaces. It represents the mechanical resistance to displacement along the insertion axis opposite to denture insertion [27]. Retention must be high enough to limit unwanted movements of the removable prosthesis while inducing reasonable lateral forces on the implant, whatever its size or angulation [19]. The adequate and satisfactory retention force for each patient remains challenging to assess [4], the minimum commonly accepted lying between 5 and 20 N while being maintained over time [11,13,14,27]. Some authors suggested that 5–7 N are sufficient for 1-IRMO [13,14,32,33], and other investigators proposed 10 N [33] or 20 N for 2-IRMO [11]. In vitro studies showed that most AS in 1 or 2-IRMO could reach this acceptable range.

BAS show retention forces in agreement with manufacturers' data, in the range of 2–16 N for 1-IRMO. However, regarding CAS for 1-IRMO, a wide range of retention forces is available through the different color-RD between 3.84 N and 16.6 N for Locator® and 13.12 and 24.03 N for ERA® [21,23] (Table 1).

Table 1. Initial retention force (Newton) of ball and cylindrical attachment systems and the influence of insertion–removal (IRC) and/or chewing cycles (CC) on the loss of retention characterized in in vitro studies. Abbreviations: ns, non-significant; Ti, titanium; TiN, titanium nitride. Negative retention loss corresponds to a gain in retention.

Studies	1 or 2-IRMO	Inter-Implant Distance (mm)	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min) Medium	Attachments System, Manufacturer	Materials		Retention Setup Before the Test (N)	Retention Force (N)		Retention Loss (%)
						Male Part	Retentive Device		Initial	Final	
Branchi et al., 2010	1	-	1 55000 IRC	54 -	Ball Ø 2.20 mm Sweden & Martina	Ti	Teflon matrix	-	13.92	17.75	27
							Red O-ring® rubber	-	10.20	2.45	75
							Gold	-	15.30	24.42	−50
							Titanium	-	13.24	4.31	68

Table 1. *Cont.*

Studies	1 or 2-IRMO	Inter-Implant Distance (mm)	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min) Medium	Attachments System, Manufacturer	Materials		Retention Setup Before the Test (N)	Retention Force (N)		Retention Loss (%)
						Male Part	Retentive Device		Initial	Final	
Yabul et al., 2018	2	19	10 5000 IRC	54 -	Ball, Biohorizons	Ti	Plastic	-	34.12 ± 4.99	11.19 ± 2.8	67.3 ± 5.74
					Ball, DTI, Istantbul		Plastic	-	26.41 ± 5.8	10.58 ± 2.96	58.9 ± 12.21
					Ball, Straumann		Gold alloy	-	48.16 ± 6.46	43.0 ± 6.30	10.5 ± 7.91
					Ball, Straumann		Titanium	-	50.39 ± 4.81	5.59 ± 2.27	88.7 ± 5.11
Elsyad et al., 2016	2	22	1 540 IRC	50 Dry	Locator®, Zest Anchors	Ti + TiN	Blue	-	19.64 ± 1.16	14.80 ± 0.83	24.64
							Pink		51.20 ± 0.83	33.60 ± 2.30	34.37
							White		65.20 ± 1.30	39.80 ± 1.48	38.95
Gamborena et al., 1997	1	-	1 5500 IRC	50 Water	ERA®, Sterngold	Gold alloy	White		14.91 ± 3.43	2.25 ± 0.49	85
							Orange		24.71 ± 3.14	2.74 ± 0.88	88
							Blue		22.75 ± 2.84	3.73 ± 0.69	85
							Gray		24.03 ± 3.53	3.43 ± 0.98	87
Stephens et al., 2014	2	22	1 5500 IRC	60 Artificial saliva	Locator®, Zest Anchors	Ti + TiN	Blue		21.81 ± 7.44	15.97 ± 3.96	5.84 ± 4.45
Choi et al., 2018	2	22	1 400,000 CC 1080 IRC	50 Demineral-ized water	Locator®, Zest Anchors	Ti + TiN	Blue	-	20.1 ± 2.87	20.58 ± 3.09	−2.81 ± 4.07
							Pink		24.55 ± 2.14	37.42 ± 2.79	−52.78 ± 7.78
							White		69.87 ± 5.73	42.56 ± 3.27	38.81 ± 5.32
					CM Loc®, Cendres & Métaux	Ti	Light Green		12.45 ± 1.27	12.83 ± 1.39	−3.01 ± 1.92
							Red		17.79 ± 1.70	21.48 ± 1.20	−22.31 ± 17.18
							Green		39.35 ± 3.45	36.99 ± 1.75	5.57 ± 5.28
							Blue		44.07 ± 3.07	43.80 ± 2.45	0.52 ± 1.92
Maniewicz et al., 2020	2	20	1 10,000 IRC	- Artificial saliva	CM Loc®, Cendres & Métaux	Ti	Red		81.8 ± 18.5	49.2 ± 12.6	39.85
					Locator R-Tx®, Zest Anchors	Ti + TiN	Pink		75.5 ± 24.9	60.0 ± 19.6	20.53
					Novaloc®, Straumann AG	Ti + ADLC	Yellow		57.7 ± 31.0	59.4 ± 16.0	−2.95
Yilmaz et al., 2020	2	-	1 1440 IRC	50 -	Locator®, Zest Anchors	Ti + TiN	Pink		13.6	10.0	26.5
					Locator R-Tx®, Zest Anchors	Ti + TiN	Pink		20.1	14.0	30.4

Table 1. *Cont.*

Studies	1 or 2-IRMO	Inter-Implant Distance (mm)	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min) Medium	Attachments System, Manufacturer	Materials		Retention Setup Before the Test (N)	Retention Force (N)		Retention Loss (%)
						Male Part	Retentive Device		Initial	Final	
Tehini et al., 2020	2	22	1 100,000 CC	60 Dry	Locator®, Zest Anchors	Ti + TiN	Blue		9.95 ± 1.91	6.37 ± 2.64	−37 ± 0.22
							Pink		15.43 ± 4.08	14.00 ± 3.89	9 ± 0.15
							White		41.73 ± 9.29	38.20 ± 5.11	7 ± 0.12
Chung et al., 2004	2	-	1	50 -	ERA®, Sterngold	Gold alloy	White	-	23.76 ± 1.02		
							Grey		35.24 ± 1.99		
					Locator®, Zest Anchors	Ti + TiN	Pink		12.33 ± 1.28		
							White		28.95 ± 0.78		
Jabbour et al., 2014 RCT/crossover	2	-	6 months	Clinical conditions	Retentive anchor, Straumann	Ti	Gold matrix		34.58 *	24.58 *	28.92 *
			12 months							20.27 *	41.38 *
			6 months		Locator®, Zest Anchors	Ti + TiN	White		39.27 *	15.47 *	60.61 *
			12 months							12.00 *	66.54 *
Gonuldas et al., 2018	2	22	1 2160 IRC	50 Dry	Ball, T.A.G. Medical Products	Ti	Orange plastic cap	-	30.7 ± 2.82	21.64 ± 1.23	29.51
							White plastic cap		47.9 ± 2.62	26.24 ± 0.71	45.22
					Locator®, Zest Anchors	Ti + TiN	Blue		61.39 ± 4.26	5.87 ± 2.42	90.44
							Pink		79.14 ± 3.63	10.4 ± 2.46	86.86
							White		93.75 ± 11.23	18.28 ± 2.25	80.50
Sultana et al., 2017	2	22	10 10,000 IRC	45 Dry	Ball, Dentsply	Ti	Red plastic cap Clix®	-	56.2 ± 6.12	46.0 ± 4.74	18.1
					Locator®, Zest Anchors	Ti + TiN	Pink		108.9 ± 29.78	20.2 ± 5.74	81.5
							Green		82.3 ± 14.15	17.3 ± 3.73	79.0
Türk et al., 2014	2	22	10 5000 IRC	50 Dry	Ball, O-Ring®, Biohorizons	Ti	Plastic cap Clix®	-	32.91 ± 5.30	9.70 ± 7.94	69.43 ± 27.61
					Locator®, Zest Anchors	Ti + TiN	Pink	-	52.47 ± 6.70	21.70 ± 10.13	57.56 ± 21.65
Wolf et al., 2009	1	-	10 50,000 IRC	- Water	Ball, Dalbo Plus®, Cendres & Métaux	Gold alloy	Gold alloy strip	7	8.86 ± 2.2	2.31 ± 1.0	77.54
						Ti	Gold alloy strip	7	9.87 ± 1.6	11.61 ± 3.7	−5.58
					Ball Ecco®, Unor	Gold alloy	Green plastic cap	8	6.97 ± 4.6	1.13 ± 0.8	88.55
					Ball Tima®, Unor	Gold alloy	Stainless steel ring	8	11.92 ± 3.1	1.55 * ± 1.4	89.82
					Ball, Pro-Snap®, Metalor Dental	Gold alloy	Green plastic cap	10	8.52 ± 2.1	3.40 ± 1.5	54.23

Table 1. *Cont.*

Studies	1 or 2-IRMO	Inter-Implant Distance (mm)	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min) Medium	Attachments System, Manufacturer	Materials		Retention Setup Before the Test (N)	Retention Force (N)		Retention Loss (%)
						Male Part	Retentive Device		Initial	Final	
Wolf et al., 2009	1	-	10 50,000 IRC	- Water	Locator®, Zest Anchors	Ti + TiN	Pink	-	13.250 ± 6.6	2.462 ± 1.8	85.66
Alsabeeha et al., 2010	1	-	10 IRC	50 -	Ball Ø 2.25 mm, Southern	Ti	Gold alloy strip	-	17.32 ± 3.68	-	
					Ball Ø 5.9 mm, Southern	Pure Ti + TiN	Plastic cap	-	32.06 ± 2.59		
					Locator®, Zest Anchors	Ti + TiN	Blue	-	3.83 ± 0.64		
							Pink		9.40 ± 0.74		
							White		12.39 ± 0.55		
Yang et al., 2011	1	-	1 IRC	60 -	Dal-ro®, Biomet 3i	Ti	Gold alloy strip	-	6.48 ± 0.34		
					Locator, Zest Anchors	Ti + TiN	Blue	-	15.36 ± 1.4		
Abi Nader et al., 2011	2	15	1 400,000 CC	15 Dry	Ball Ø 2.25 mm, Nobel Biocare	Ti	Gold alloy	1 turn	10.6 ± 3.6	7.9 ± 4.3	25.47
					Locator®, Zest Anchors	Ti + TiN	White	-	66.4 ± 16.0	21.6 ± 17.0	67.47
Petropoulos et al., 2011	2	-	1	50.8 -	Ball Ø 3.5 mm, Nobel Biocare	Ti	Rubber O-ring®	-	24.3		
					Ball Ø 2.25 mm, Nobel Biocare	Ti	Ti cap/Ti spring	-	17.8		
					Zest®, Zest Anchors	-	-	-	10.8		
					ZAAG®, Zest Anchors	-	-	-	37.2		
					ERA®, Sterngold	-	White	-	12.7		
							Orange		18.5		
Kobayashi et al., 2014	2	20	10 14,600 IRC	4000 NaCl 0.9%	Retentive Anchor, Straumann	Ti	Gold alloy	7 (0.5 turn)	40.3 ± 15.83	67.9 * ± 15.83	−68.48 (-)
					Locator®, Zest Anchors	Ti + TiN	Blue	-	33.5 ± 9.77	24.57 ± 12.35	26.66
Saheli et al., 2019	2	19	1 1440 IRC	50 -	Ball, Dio Implant, Dio Corp	Ti	-	-	15.6	9.3	40.38
		23							15.3	8.0	46.20
		29							13.8	10.2	26.07
		19			Locator®, Zest Anchors	Ti + TiN	-	-	17.1	5.2	69.59
		23							33.5	8.0	76.12
		29							33.1	6.8	79.46
Scherer et al., 2014	2	Inter-canine	1 IRC	50.8	Ball, Zimmer Dental	Ti	White cap	-	35.23	-	
					Ball O-ring® Saturno Standard, Zest Anchors	Ti	Rubber ring		13.13		

Table 1. *Cont.*

Studies	1 or 2-IRMO	Inter-Implant Distance (mm)	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min) Medium	Attachments System, Manufacturer	Materials		Retention Setup Before the Test (N)	Retention Force (N)		Retention Loss (%)
						Male Part	Retentive Device		Initial	Final	
Scherer et al., 2014	2	Inter-canine	1 IRC	50.8	ERA®, Sterngold	-	Orange	-	9.36	-	
					Locator®, Zest Anchors	Ti + TiN	Pink		26.64		
Rutkunas et al., 2011	1		1 15,000 IRC	50 Demineralized water	OP Anchor®, Inoue A. Co. Ltd.	Gold alloy	Rubber ring	-	3.15 ± 0.6	3.70 ± 0.2	−17.4
					ERA®, Sterngold	Gold alloy	White	-	13.12 ± 3.3	2.89 ± 0.7	87
							Orange		12.63 ± 1.4	2.86 ± 0.5	88
					Locator® Root, Zest Anchors	Stainless steel + TiN	Blue		16.50 ± 9.4	6.24 ± 6.1	62.18
							Pink		15.20 ± 6.9	11.95 ± 3.5	21.38
							White		16.61 ± 2.2	10.28 ± 3.9	38.11

For 2-IRMO, initial retention is generally equal to or greater than twice the retention provided by a single AS. It ranges between 10.6 N and 56.2 N for BAS and between 9.95 N and 108.9 N for CAS (Table 1) depending on the chosen AS and RD (9.95–108.9 N for Locator®, 20–75 N for Locator R-Tx®, 57 N for Novaloc®, 12.45–44.07 for CM Loc®, and 12.7–35.24 N for ERA®). Higher retention may be related to unwanted misalignment between implant axes or between implants and insertion axes due to inaccuracies in implant positioning and in controlling the direction of dislodgment in vitro. Despite many studies (ERA® vs. Locator® [34], Locator® vs. CM-Loc® [27], Novaloc® vs. Locator® R-Tx vs. CM Loc® [30], Locator® vs. Locator R-Tx® [35]), a direct comparison of initial retention between different CAS remains difficult because of their large choice of RD.

Several in vitro studies have compared the initial retention force of BAS and CAS. Five studies [5,13,21,32,36] presented in Table 1 observe greater retention forces for CAS (especially Locator® and ERA®) over BAS (OP Anchor®, O-Ring®, Pro-Snap®, Ecco®, and Dalbo Plus®) even if the values vary between studies. This could be explained by larger friction surfaces observed in CAS between the cylindrical abutments and the RD compared to the linear contact located at the ball's equator in BAS. Three contradictory studies found greater retention for BAS with plastic RD [11,33] or metallic lamellae [16] compared to the Locator®. These results could be explained by the use of a larger implant (8 mm) with AS diameter (5.9 or 7.9 mm) [11], anecdotic in our clinical context, and a considerable variation in standard deviations which raises questions on the methodology applied (40.3 ± 15.83 N for Dalbo Plus® and 33.5 ± 9.77 N for Locator®) [16].

In conclusion, the few comparative in vitro studies agree that the initial retention force of CAS (Locator®) is more significant than BAS, even if the tested RD and the experimental conditions vary between studies. However, this superiority does not seem to be felt clinically, according to Krenmair et al. that showed similar patient satisfaction for the two types of attachment during 3 months of wearing [6].

3.2. Maintenance, Wear and Loss of Retention of BAS and CAS

The maintenance of an IRMO encompasses a multitude of parameters that are not all specific to the presence of AS in prosthetic construction and vary considerably between studies (Table 2). It concerns male and female parts of AS, mandibular overdenture, opposite prosthesis, peri-implant or soft tissue-related complications, and quality of life. To

provide a good integration of the prosthesis over time, dental practitioners need to regularly modify its shape in order to adjust over-extensions and dental occlusion [12] or repair the prosthesis (overdenture replacement, fractures, removable relining procedures) [3]. Maintenance of the AS generally occurs in the first year after the prosthetic insertion [2,8,17] and is more prevalent during the first 4 years [8]. The most common complication is the loss of retention, mainly due to wear of the RD generated by repetitive mechanical loading, which requires its activation [8,37] or replacement after a mean time estimated at 11.2 months [3,7,38]. This event affects all patients, and it can occur up to 7 times per AS after 10-year follow-up in 1-IRMO [39]. RD of BAS can be activated (gold alloy) or replaced (rubber ring, nylon or plastic cap, circular stainless steel spring), whereas RD of CAS can only be replaced (polyethylene or PEEK caps). Other complications could be the management of abutment or RD loss or the fracture of the male and female parts, which remain exceptional [3,8,16,19]. According to some authors [8,9,12], AS is considered successful if there are no more than two activations, repairs, or replacements of either patrix or matrix in the first year of clinical use. Considering the overdenture, success is characterized by no more than one relining to improve fit and stability.

Table 2. Prosthodontic maintenance of 1- or 2-implant-retained mandibular overdentures and their ball or cylindrical attachment systems. Abbreviations: nc, non-communicated; H, hauteur; RD, retention device; RCT, randomized clinical trial, Ø, diameter.

Clinical Studies Types Follow-Up	Attachment Systems (Male Part/Female Part/Manufacturer)	1 or 2-IRMO	Number of Patients	Maintenance of the Attachment System				Maintenance of the Overdenture			Total Number of Events
				Activated RD	Replaced RD	Replaced Matrix Housing	Tightened or Replaced Patrix	Relined Denture	Fracture or Occlusal Adjustment	Replaced Denture	
Cune et al., 2004 Prospective 1 year	Titanium ball/Gold alloy RD/Friadent, Mannheim, Germany	2	18	7	-	1	1+4	nc	nc	nc	13
Mackie et al., 2011 RCT 8 years	Titanium ball Ø 2.25-mm/Gold RD/Straumann, Basel, Switzerland	2	17	9.6 ± 13.5	1.1 ± 3.2	nc	nc	nc	nc	nc	3.9 ± 2.1
	Titanium ball Ø 2.25-mm/Gold RD/Brånemark, Nobel Biocare		10	18.0 ± 19.8	5.5 ± 7.7	nc	nc	nc	nc	nc	28.8 ± 12.6
	Titanium ball Ø 2.25-mm/Gold-platinum RD/Southern Implants		11	11.9 ± 11.8	2.2 ± 4.4	nc	nc	nc	nc	nc	16.4 ± 7.5
	Titanium ball Ø 2.25-mm/Titanium RD/Straumann, Basel, Switzerland		9	-	13.7 ± 14.7	nc	nc	nc	nc	nc	24.9 ± 10.7
	Titanium ball Ø 3.95-mm/Plastic RD/Southern Implants		22	-	4.3 ± 7.6	nc	nc	nc	nc	nc	8.7 ± 4.2
	Titanium ball Ø 2.2-mm/Rubber ring RD/Steri-Oss (Locator®/Zest Anchors after 6 years)		21	-	29.2 ± 24.3	nc	nc	nc	nc	nc	32.2 ± 14.5

Table 2. *Cont.*

Clinical Studies Types Follow-Up	Attachment Systems (Male Part/Female Part/Manufacturer)	1 or 2-IRMO	Number of Patients	Maintenance of the Attachment System				Maintenance of the Overdenture			Total Number of Events
				Activated RD	Replaced RD	Replaced Matrix Housing	Tightened or Replaced Patrix	Relined Denture	Fracture or Occlusal Adjustment	Replaced Denture	
Nogueira et al., 2018 Prospective 2 years	Nitrite-coated titanium ball/Nylon RD/Neodent, Curitiba, Paraná, Brazil Titanium ball/Rubber ring/Conexão Sistemas de Prótese, Arujá, Brazil	1	45	-	66	12+7	7+6	3	23	nc	124
Passia et al., 2019 Prospective 10 years	Titanium ball, Camlog Biotechnologies, Switzerland/Gold RD, Dalbo- Plus Elliptic, Cendres & Métaux, Biel, Switzerland	1	11	29	23	nc	5+4	14	8	nc	83
Walton et al., 2009 RCT 1 year	Titanium retentive anchor/Gold RD/Straumann, Basel, Switzerland	1	42	37	4	0	5	60	4+5+2	nc	159
		2	44	34	4	2	1	44	2+2	nc	81
Alsabeeha et al., 2011b RCT 1 year	Uncoated standard titanium ball Ø 2.25-mm/Dalla Bona–type Gold alloy RD/Southern Implants	1	12	13	0	nc	0+2	nc	nc	nc	15
	Titanium nitride–coated ball Ø 5.9-mm/Plastic cap RD/Southern Implants		12	-	2	nc	0	nc	nc	nc	2
	Titanium nitride–coated abutment/Blue nylon cap RD/Locator®, Zest Anchors, Escondido, CA, USA		12	-	16	nc	0	nc	nc	nc	16
Cristache et al., 2014 RCT 5 years	Titanium retentive anchor, H 3.4 mm/Gold RD Elitor®/Straumann, Basel, Switzerland	2	12	144	8	nc	1	4	2+0	2	161
	Titanium retentive anchor H 3.4 mm/Titanium RD and stainless steel spring, 6.86–10.79 N/Straumann, Basel, Switzerland		11	-	0	0	2	2	1+0	1	6
	Titanium nitride–coated abutment H 3 mm/Pink nylon cap/Locator®, Zest Anchors, Inc., Escondido, CA, USA		23	-	22	nc	0	1	0	1	24
Kleis et al., 2010 RCT 1 year	Dal-Ro®, Biomet 3i Implant Innovations, Palm Beach Gardens, FL, USA	2	25	4	0	0	1	nc	1	nc	6
	TG-O-Ring® ball/Rubber ring RD/ Cendres & Metaux SA, Biel-Bienne, Switzerland		8	-	10	3	1	nc	0	nc	14
	Locator®, Zest Anchors, Escondido, CA, USA		23	-	24	4+4	2	nc	1	nc	35

Table 2. *Cont.*

Clinical Studies Types Follow-Up	Attachment Systems (Male Part/Female Part/Manufacturer)	1 or 2-IRMO	Number of Patients	Maintenance of the Attachment System				Maintenance of the Overdenture			Total Number of Events
				Activated RD	Replaced RD	Replaced Matrix Housing	Tightened or Replaced Patrix	Relined Denture	Fracture or Occlusal Adjustment	Replaced Denture	
Krenmair et al., 2012 RCT/ crossover 1 year	Ball abutment/Gold RD/Camlog, Screw-line, Altatec)	2	10	2	0	nc	1+1	5	0+1	0	10
	Locator® abutment/Pink RD/Zest Anchors, Inc., Escondido, CA, USA		9	-	4	nc	1	4+1	1	0	11

Different paradigms correlate in vitro mechanical loading with an estimated wearing time. Some studies use insertion–removal cycles (IRC) with different numbers of cycles per day: 3 [12,40], 4 [16,41,42] or 5 [21]. Others consider only chewing cycles (CC) [13] or a combination of CC and IRC [27]. Depending on the study, one year of clinical use would be equivalent to 1000–1800 IRC or 400,000 CC. Based on this estimation, some in vitro studies [5,29] characterized retention loss and wear of the AS for a number of cycles equivalent to more than 15 years of service, that far exceeds the mean time between two activations or replacements estimated at 11.2 months [3,7,38]. An equivalent wearing time is systematically indicated in the following presentation of in vitro results to highlight this correlation.

Wear is defined as material loss due to contacts between the matrix and the patrix, which increases the gaps between the different parts [2,41]. In the oral cavity, wear, mainly caused by mechanical loading (chewing and insertion/removal of the prosthesis), is located more in the labiolingual direction than in the mesiodistal one, and is increased when implants are inclined with respect to the insertion axis of the prosthesis [17,29,41]. Besides mechanical factors, environmental factors, including temperature change or aggressive bathing solutions, can also alter AS, especially polymeric RD [29]. Sometimes, damages are caused by the tools used to insert, remove, or activate the RD in the matrix housing during maintenance [13]. In the short or medium term, studies have shown that wear occurs at the equator of titanium abutments discreetly and similarly with no measurable change in diameter regardless of the AS [3,5]. Different surface wear patterns (Table 3) appear according to the type of RD and its constitutive material [4]. For all AS, RD was designed in the less rigid material to wear out preferentially, its replacement being more manageable and less expensive, leaving the abutment (patrix) intact. All analyzed clinical and in vitro studies conclude that loss of retention over time concerns both BAS and CAS but in different proportions [6,7,13,36,41]. The IRC and/or CC, performed by the patients in clinical studies or automatically in in vitro studies (fatigue tests) gradually decrease retention (Table 1).

Table 3. Wear patterns and dimensional changes of ball and cylindrical attachment systems in clinical and in vitro studies. Abbreviations: RCT, randomized clinical trial; SEM, scanning electron microscope; Ø, diameter.

Studies Types 1- or 2-IRMO Follow-up	Attachment System, Manufacturer	Number of AS	Assessed Parameters/Methods	Results and Location	
				Patrix	Matrix
Alsabeeha et al., 2011b RCT 1-IRMO 1 year	Titanium nitride–coated ball Ø 5.9-mm/Plastic cap RD/Southern Implants	5/12	Wear patterns/SEM Composition of particles/Energy dispersive spectrometer	Unaffected	Slight signs of wear
	Uncoated standard titanium ball Ø 2.25-mm/Dalla Bona–type Gold alloy RD/Southern Implants	5/12		Extensive material loss and abrasion along the path of insertion–removal and across the circumference	Extensive plastic deformation, material flaking and sloughing
	Titanium nitride–coated abutment/Blue nylon cap RD/Locator®, Zest Anchors	5/12		Unaffected	Surface rupture and material loss (central core)
Fromentin et al., 2011a Retrospective clinical study 2-IRMO 8 years	Titanium ball anchor/Gold alloy RD Elitor®/Straumann	144 (male and female parts)	Wear patterns/SEM Composition of particles/Energy dispersive spectrometer	Year 1: Slight scratches only at the equator Year 3: Slightly deformed profile, scratches at the equator and the summit Year 8: deformed and off-center ball	Year 1: Roughening, and material loss in the form of flakes Year 3: Blunt and deformed lamellae edge along their entire length Year 8: Fatigue cracks or fracture, increased matting of the inner surface, welding of the lamellae
Fromentin et al., 2011b Retrospective clinical study 2-IRMO 8 years	Titanium ball anchor (Ø 2262 to 2267 µm)/Gold alloy RD/Straumann, Basel, Switzerland	69 patrices + 10 controls	Measure of ball Ø, calculation of Ø loss and deviation from circularity in 3 different axes (Vertical V, Mesio-Distal MD, Bucco-Lingual BL)/Coordinate measuring machine with a touch trigger probe	Year 1 (24 AS): Ø 5 to 7 µm (20–23%). Significant more loss in BL but no significant difference in Ø reduction Year 3 (29 AS): Ø 19 to 22 µm (61–91%), significant more loss in BL, 90% at the equator Year 8 (16 AS): Ø 22 to 31 µm. Significant more loss in BL and V	
Fromentin et al., 2012 Retrospective clinical study 2-IRMO 8 years	Titanium ball anchor, Straumann AG, Basel, Switzerland/Gold alloy RD (Ø 2973/2214/2300 µm, E 380/336 µm), Cendres+Metaux, Biel, Switzerland	70 matrices + 10 controls	Measure of the external, internal upper and internal lower matrix Ø and deviations from circularity. Calculation of the upper and lower thickness (E) and the thickness loss of the lamellae tip/Coordinate measuring machine with a touch trigger probe		Year 1 (26 AS): Ø 2989/2232/2298 µm; E 373/342 µm, loss 7 µm. Significant increase of the internal upper Ø, no difference of deviation of circularity in the 3 different areas Year 3 (28 AS): Ø 2937/2282/2309 µm, E 33/316 µm, loss 47 µm. Year 8 (16 AS): Ø 2944/2304/2307 µm, E 310/308 µm, loss 70 µm. In years 3 and 8: increase of the internal upper Ø while the external Ø were significantly lower. Significant increase of deviation from circularity

Table 3. *Cont.*

Studies Types 1- or 2-IRMO Follow-up	Attachment System, Manufacturer	Number of AS	Assessed Parameters/Methods	Results and Location	
				Patrix	Matrix
Jabbour et al., 2014 RCT/Crossover 2-IRMO 1 year x2	Retentive Anchor/Gold RD/Straumann, Burlington, ON, Canada	48	Wear patterns/SEM	No significant scratches, minor flattening (equatorial zone)	nc
	Locator® abutment/White nylon RD/Zest Anchors, Escondido, CA, USA	48	Wear patterns/SEM + high-resolution µCT	No significant scratches and spots	Significant wear and plastic deformation (peripheral notch edge, central core edge)
Abi Nader et al., 2011 In vitro 2-IRMO 400,000 CC (1 year) Dry condition	Titanium ball/Gold lamellae RD/Nobel Biocare	4/16	Wear patterns/SEM	Discrete wear (top and lateral zone part of ball)	Slight wear and discrete deformation, probably due to the activator tool (internal surfaces, corners of retentive lamellae)
	Titanium nitride-coated abutment/nylon RD/Locator®, Zest Anchors, Escondido, CA, USA	4/16		Deformation possibly caused by the specific tool (inner surface of the retentive area)	Severe wear (central core and periphery)
Choi et al., 2018 In vitro 2-IRMO 400,000 CC and 1080 IRC (1 year) Deionized water	Pure titanium abutment/Green, Red, Light Green and Blue PEEK RD/CM Loc®, Cendres & Métaux	1/20	Wear patterns/SEM	No noticeable abrasion	Slight wear, probably from tools used for placement (top and along the vertical split)
	Titanium nitride–coated abutment/Blue, Pink and White nylon cap RD/Locator®, Zest Anchors	1/20		No noticeable abrasion	Severe wear, plastic deformation, surface irregularities, loss of materials more than PEKK RD (retention area, top of central core and periphery)
Gamborena et al., 1997 In vitro 1-IRMO 5500 IRC (3 years) Water	White, Orange, Blue and Grey RD/ERA®, APM-Sterngold	3/5	Wear patterns and dimensional Ø changes (top and middle part of central core, metal inner ring of matrix housing)/Traveling three-dimensional microscope		No difference between new and worn matrix housing. Ø loss of central core: −1.80 to +3.54%. The difference (statistical) in Ø between the matrix housing and the middle portion of the RD ranged from 72 to 126 µm
Rabbani et al., 2015 In vitro 2-IRMO 2160 IRC (nc) Artificial saliva	Blue, Pink and White RD/Locator®, Zest Anchors, Inc., Escondido, CA	30	Wear patterns/SEM	nc	Significant wear (retention area, central core, periphery)
Rutkunas et al., 2011 In vitro 1-IRMO 15,000 IRC (nc) Demineralized water	Gold alloy ball/rubber ring/OP Anchor®, Inoue Attachments Co., Tokyo, Japan	2/5	Wear patterns and dimensional changes/SEM		No Ø loss: 0.52%
	Gold alloy abutment/nylon RD (Orange, White)/ERA®, Sterngold, Attleboro, USA	2/5			Ø loss: 0 to 2.48%, smooth surfaces (central core and inner peripherical surface)
	Stainless steel TiN coated abutment/nylon RD (Blue, Pink, White), Locator® Root, Zest Anchors, Escondido, USA	2/5			Ø loss: 0.22 to 5.34%, surface particle loss and irregular surface (central core and inner peripherical)

Table 3. *Cont.*

Studies Types 1- or 2-IRMO Follow-up	Attachment System, Manufacturer	Number of AS	Assessed Parameters/Methods	Results and Location	
				Patrix	Matrix
Stephens et al., 2014 In vitro 5500 IRC (nc) Artificial saliva	Blue RD/Locator®, Zest Anchors, Inc., Escondido, CA	20	Wear patterns/SEM	No visible wear	Severe wear (central core > matrix housing)
Türk et al., 2014 In vitro 5000 IRC (nc)	Ball abutment/Rubber ring RD/O-Ring®, Biohorizons	10	Dimensional changes (outer and inner diameters of the abutments)/SEM	nc	Ø loss: outer (0.14 ± 0.07mm) and inner (0.08 ± 0.08 mm)
	Locator®, Zest Anchors, Inc., Escondido, CA	10		nc	Ø loss: outer (0.17 ± 0.11 mm), inner: 0.11 ± 0.14 mm. No significant difference between the two AS
Wolf et al., 2009 In vitro 1-IRMO 50,000 IRC (nc) Water	Precious alloy ball/Titanium matrix housing with precious alloy RD/Dalbo-Plus®, Cendres & Metaux	1	Wear patterns/SEM	Noticeable signs of abrasion	nc
	Titanium ball/Titanium matrix housing with precious alloy RD/Straumann	1		Slight grooves at the equator without any measurable changes in Ø	Minor wear at the tips of the metal lamellae
	Precious alloy ball/Titanium matrix housing with Green plastic RD/Ecco®, Unor	1		Large grooves at the equator without any Ø loss	Obvious damages
	Precious alloy ball/Titanium matrix housing with stainless steel spring/Tima®, Unor	1		Extensive signs of wear at the equators with Ø loss	Fractures of the retention springs
	Precious alloy ball/Titanium matrix housing with Red plastic RD/Pro-Snap®, Metalor	1		Little signs of abrasion at the equator	nc
	Titanium-nickel coating abutment/Stainless steel housing with Pink RD/Locator®, Zest Anchor	1		Little abrasion at the equator	Considerable signs of wear
Yabul et al., 2018 In vitro 2-IRMO 5000 IRC (4.5 years)	Ball/Gold RD/Straumann AG, Basel, Switzerland	24	Wear patterns and volumetric loss of ball/Three-dimensional laser scanner	0.7 ± 0.47%	
	Ball/Titanium RD/Straumann AG, Basel, Switzerland	24		25.38 ± 5.41%	
	Ball/Plastic RD/Biohorizons, Birmingham, Alabama	24		12.94 ± 1%	
	Ball/Plastic RD/DTI, Istanbul, Turkey	24		10.47 ± 1.7%	

Concerning BAS, retention is ensured mainly by the friction between two metallic surfaces (titanium patrix/precious alloy or stainless steel matrix) and sometimes between metallic and polymeric surfaces (titanium patrix/polyacetal or rubber ring matrix). Wear including abrasion and scratches can exceptionally affect the patrix—diameter reduction

up to 25% observed with an anecdotic titanium RD after 5000 IRC (3 years) [43]—but affects the matrix essentially [6–9,15,17,41,44].

Clinical studies about BAS showed that wear of the precious alloy RD in contact with the titanium alloy ball abutment generated blunt lamella edges with a loss of RD thickness (1 year: 7 µm, 3 years: 47 µm, and 8 years: 70 µm) [41,44], and gold or titanium deposits on the RD [15,41]. Two clinical studies even described a significant wear of a titanium ball abutment (patrix) with precious alloy RD, increasing between the first and third years and remaining stable until 8 years [4,17], characterized by a flattening of the surface [15], an eccentricity of the ball in the long term and a reduction in diameter at the equator (1 year: 5–7 µm, 3 years: 19–22 µm, 8 years: 22–31 µm) [41]. Scratches were also observed in vitro [5], after 50,000 IRC (30 years) on ball abutments associated with metallic RD. It appears that the combination of titanium alloy ball with precious alloy RD or with plastic cap remains the most favorable configuration overtime to limit the loss of retention or to reduce post-insertion aftercare. Indeed, their initial and final retention are similar, although a retention increase (up to 65% of the initial retention) is observed up to 15,000 CC (2 weeks) or 500 IRC (4 months), which is maintained in the case of IRC until 5500 IRC (3 years) [45] or followed by a slight decrease in case of CC to return to its initial value at 100,000 CC (3 months) [5,13,16,21], maintained until 400,000 CC (1 year) [5,8,13].

Concerning CAS, friction involves only metal and polymer surfaces (titanium patrix/nylon or PEEK matrix). In vitro [21,25] and clinical [4] studies showed excessive wear of the nylon RD of Locator® AS with the presence of mineral deposits coming from the titanium alloy abutment [15], that required RD replacement, the abutment presenting little or no abrasion [3,5,11,13,21,27]. The dimensional changes and deformations prevailed on the central core of Locator® RD (loss of substance and surface irregularity) [21,25] and ERA® nylon RD (>5.0% surface smoothing) [21], compared to their periphery (2.1%) or the metallic matrix housing (0.9%) [21]. The wear pattern of PEEK RD (Novaloc® or CM Loc®) is not well established: one in vitro study showed severe deformation after 30,000 IRC (16 years) [29], while another none after 400,000 CC (1 year) [27]. ERA®, Locator® and CM Loc® RD decrease significantly in long term retention, and in particular for Locator® (66 to 75% of their initial retention) compared to CM Loc® (32 to 47%) after 30,000 IRC (16 years) [29], and this appears earlier for ERA® RD (85% after 1000 IRC/1 year) [21,23]. In general, for Locator®, a significant decrease in retention is even observed during the first 10 to 20 IRC, but retention loss remains not significant after 100,000 CC (3 months) [13,46]. Nevertheless, a progressive decrease is observed until 1000 to 2000 IRC (i.e.,1 to 2 years of clinical service) [5,10,13,35,41]. Concerning other CAS, no significant difference between initial and final retention was found at 5000 IRC (3 years) for CM Loc® [27,29] and at 10,000 IRC (6 years) for Novaloc® and Locator R-Tx® [30].

The remarkable mechanical properties of PEEK (tensile and bending strength, fatigue behavior) [27] could explain the increased performance of Novaloc®. Also, its RD design present a vertical slit that expands during the IRC or CC, thus reducing the deterioration of the material. In addition, for Novaloc® and Locator R-Tx®, manufacturers provide color-RD associated with different levels of retention and wear behaviors. The variable selection of RD among studies can explain differences observed in wear and retentive properties.

Comparative clinical [4,6,7,15] and in vitro [9,13,32] studies between BAS and CAS concluded that ball precious alloy strips RD presented lower surface wear, and needed less or equivalent post-insertion maintenance than Locator® RD. Only Cristache et al. [9] found a higher maintenance requirement for BAS after 5 years, using an obsolete version of gold alloy RD. Even if the experimental conditions are different (study design, number of implants, number of cycles, follow-up period), all except two [9,32] agree that Locator® loses more retention than BAS [3,6,15,21]. This decrease evaluated up to 40% after 400,000 CC (1 year) [13], and to 66–75% after 30,000 IRC (16 years) [29] is mainly attributed to the nylon RD wear, which is more frequent in this system both in vitro and clinically [7,13]. In one clinical study, retention loss is evaluated at 70% of initial retention for the Locator® (including 50% in the first 3 months) and only 40% for the ball after 2 years [15]. Conversely, the

retention of BAS is more stable over time, with a nonsignificant decrease after 400,000 CC (1 year) (less than 10% of the initial retention force) [13]. Nevertheless, despite a more significant loss of retention for Locator®, its retention force, after 1 to 2 years of wearing, remains higher [13] or similar [5] to BAS.

In conclusion, contact surfaces must be made in different materials (polymer RD/titanium abutment or precious alloy RD/titanium abutment) to limit wear and retention loss. Abi Nader et al. [13] estimated that the Locator®, which has higher initial retention, would lose its superiority over the ball after 300,000 CC (9 months), leading to a nonsignificant difference in the final retention between the two AS, after one year of clinical service (400,000 CC). This difference might have a clinical relevance according to the initial retention needed and the interval between two maintenance sessions (activation or replacement of RD) [16]. Both clinical acts require minimal chair-time [6]. The practitioners will then choose the AS depending on the frequency of maintenance appointments, the initial retention force needed, and their usage preferences.

3.3. Influence of Implant Parameters on Retention, Wear and Maintenance of AS

The previously analyzed in vitro studies only concerned parallel implants placed under optimal conditions. However, initial retention, loss of retention, wear, and postinsertion aftercare would occur much sooner in a clinical context. The prosthetic construction on the opposing arch (removable or fixed overdentures, full or partially dental arch), prosthetic hygiene, regular dental aftercare sessions and implant parameters (implant angulation, interimplant distance, angulation between implant and AS) can easily be tuned in in vitro studies. Their impact on retention and wear of AS is presented in the following sections.

According to the clinical context, when a 2-IRMO is indicated, the two implants should be placed (i) parallel to the vertical path of insertion and (ii) parallel to each other in the interforaminal region (Figure 5). However, due to anatomical constraints or surgeon experience [10,25,47], the ideal orientation of implants is sometimes impossible to reach, and angulation is often observed between the two implants [47]. Indeed, without a surgical guide, experienced practitioners manage to place the implants with an interimplant angulation of 4.6 $\pm$ 2.9 degrees in the coronal plane and 3.5 $\pm$ 2.6 degrees in the sagittal plane [15]. Moreover, an angulation between implants of more than 6 degrees in the sagittal or 6.5 degrees in the frontal plane requires a significantly higher number of denture adjustments [10] and affects AS retention and wear. Although it remains clinically tricky to achieve a 0-degree angle, practitioners should try to reach for the lowest interimplant angulation [25], especially projected in the sagittal plane because the wear is more important in the labio-lingual direction [15]. It is difficult to categorically state the influence of implant or interimplant angulation (α and β, Figure 5) on retention for any type of attachment, notably for CAS because of the scattering of the results presented in Table 4. This discrepancy may be related to the use of four chains connected to the prosthesis to impose its vertical displacement in most studies [27,33,47,48]. The orientation of the insertion/disinsertion axis may vary between each test, affecting the measured retention force and modifying the intended implant angulation. Perfect control of the dislodging axis can only be ensured by a rigid connection between the prosthesis and the loading machine or by actual measurement of the chains' orientations for each cycle.

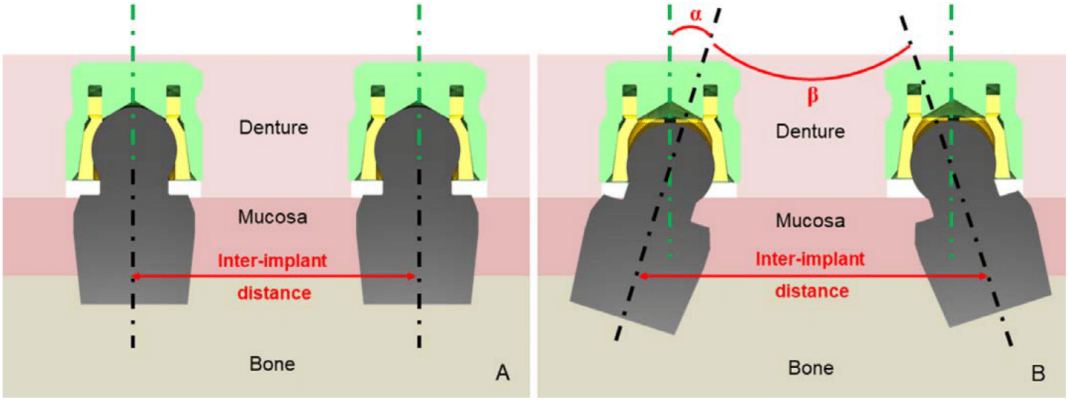


Figure 5. Overdenture with two parallel attachments on (**A**) two parallel implants, and (**B**) two non-parallel implants. Green axis: axis of insertion–removal of the denture. Black axis: axis of the implant. α: implant angulation. β: inter-implant angulation.

Table 4. Influence of implant angulation on the initial retention force and after insertion–removal (IRC) and/or chewing cycles (CC) of selected ball and cylindrical attachment systems. Negative retention loss corresponds to a gain in retention.

In Vitro Studies	1 or 2 IRMO	Inter-implant Distance (mm)	Angulation	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min)	Medium	Attachment Systems/Retentive Device	Implant Angulation α (°)	Retention Force (N)		Retention Loss (%)
									Initial	Final	
Ortégon et al., 2009	2	20	Distal	1 3500 IRC	50	nc	Ball Astra-Tech/PreciClix® RD	0 (0 RD)	nc	20.11 ± 2.51	nc
								10 (0 RD)	nc	21.31 ± 1.79	nc
								15 (0 RD)	nc	18.73 ± 4.14	nc
								10 (10 RD)	nc	19.93 ± 1.38	nc
								15 (15 RD)	nc	16.84 ± 1.77	nc
Elsyad et al., 2018	2	22	Mesial	1 540 IRC	50	nc	Locator®/Blue	0	20.63 ± 0.70	3.52 ± 0.46	82.94
								5	15.90 ± 0.65	24.02 ± 0.97	51.07
								10	28.07 ± 1.01	26.28 ± 0.62	63.77
								20	47.44 ± 0.51	30.56 ± 0.51	35.58
							Locator®/Pink	0	40.07 ± 0.90	19.15 ± 0.78	52.21
								5	30.13 ± 0.82	31.23 ± 0.68	−3.65
								10	31.57 ± 0.51	16.16 ± 1.04	48.81
								20	56.18 ± 0.75	36.45 ± 1.50	35.12
							Locator®/White	0	49.20 ± 0.72	32.01 ± 0.01	34.94
								5	40.26 ± 1.10	41.14 ± 1.03	−2.18
								10	41.06 ± 1.00	19.05 ± 0.93	53.60
								20	57.28 ± 0.63	19.99 ± 1.00	65.10

Table 4. *Cont.*

In Vitro Studies	1 or 2 IRMO	Inter-implant Distance (mm)	Angulation	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min)	Medium	Attachment Systems/Retentive Device	Implant Angulation α (°)	Retention Force (N)		Retention Loss (%)
									Initial	Final	
Elsyad et al., 2019	2	22	Distal	1 540 IRC	50	nc	Locator®/Blue	0	20.63 ± 0.70	3.52 ± 0.47	82.94
								5	15.29 ± 0.61	9.13 ± 0.81	40.29
								10	30.16 ± 1.25	2.97 ± 1.05	90.15
								20	17.08 ± 0.88	30.26 ± 0.65	−77.17
							Locator®/Pink	0	40.07 ± 0.90	19.15 ± 0.78	51.40
								5	34.60 ± 0.53	16.31 ± 1.14	52.86
								10	47.10 ± 0.85	9.11 ± 1.02	80.66
								20	39.12 ± 1.02	21.10 ± 1.01	46.06
							Locator®/White	0	48.20 ± 0.72	32.02 ± 1.00	33.57
								5	43.13 ± 1.20	44.01 ± 1.00	−2.04
								10	49.25 ± 1.39	40.18 ± 1.05	18.42
								20	40.30 ± 1.13	41.32 ± 1.50	−2.53
							Locator®/Green	20	27.50 ± 0.50	15.42 ± 0.52	43.93
							Locator®/Red	20	38.23 ± 1.08	20.14 ± 1.03	47.32
Rabbani et al., 2015	2	23	Mesial	1 2160 IRC	nc	nc	Locator®/Blue	0/0	77 ± 13.5	25.8 ± 5.2	65.5 ± 10.2
								0/10	66.4 ± 26.7	14.7 ± 7.9	70.6 ± 22.9
								5/5	73.7 ± 10.1	18.4 ± 3.7	74.1 ± 7.9
							Locator®/Pink	0/0	72.7 ± 1.3	27.7 ± 8.2	62.1 ± 10.7
								0/10	74.8 ± 6.7	31.3 ± 4.1	35.1 ± 2.4
								5/5	71.4 ± 3.4	29.4 ± 2.7	30.2 ± 2.7
							Locator®/White	0/0	83.8 ± 10.9	32.0 ± 10.7	62.1 ± 9.6
								0/10	101.32 ± 12.0	35.1 ± 2.4	65.1 ± 4.2
								5/5	89.5 ± 15.7	30.2 ± 2.7	65.1 ± 9.4
Stephens et al., 2014	2	22	Distal	1 5500 IRC	60	Artificial saliva	Locator®/Blue	0	21.81 ± 7.44	15.97 ± 3.96	26.78
								5	30.03 ± 6.24	15.43 ± 1.59	48.62
								10	24.75 ± 6.83	14.22 ± 2.43	42.54
Al-Ghafi et al., 2009	2	15	nc	1 14,400 IRC	nc	nc	Locator®/Green	0	81.75	nc	nc
								5	91.74	nc	nc
								10	104.72	nc	nc
								15	84.86	nc	nc
								20	78.04	nc	nc
Passia et al., 2016	1	-	nc	10 30,000 IRC	nc	Water	Locator®/Green	0	21.5	nc	66
								20	24.4	nc	75
							CM Loc®/Green	0	22.5	nc	32
								20	27.4	nc	47
Choi et Jeong, 2018	2	22	Distal	1 400,000 CC & 1080 IRC	50	Deionized water	Locator®/Blue	0	20.1 ± 2.87	20.58 ± 3.09	−2.81 ± 4.07
								10	22.94 ± 1.48	25.03 ± 2.59	−8.93 ± 5.99
							Locator®/Pink	0	24.55 ± 2.14	37.42 ± 2.79	−52.78 ± 7.78
								10	47.13 ± 8.96	30.33 ± 4.18	34.77 ± 6.82
							Locator®/White	0	69.87 ± 5.73	42.56 ± 3.27	38.81 ± 5.32
								10	56.86 ± 4.44	39.55 ± 2.95	30.19 ± 5.50
							CM Loc®/Green (extralight)	0	12.45 ± 1.27	12.83 ± 1.39	−3.01 ± 1.92
								10	12.11 ± 1.28	15.52 ± 1.41	−30.52 ± 23.84
							CM Loc/Red (light)	0	17.79 ± 1.70	21.48 ± 1.20	−22.31 ± 17.18
								10	27.63 ± 2.28	26.74 ± 2.42	3.25 ± 2.69
							CM Loc®/Green (medium)	0	39.35 ± 3.45	36.99 ± 1.75	5.57 ± 5.28
								10	46.96 ± 1.70	43.84 ± 1.99	6.55 ± 5.01

Table 4. *Cont.*

In Vitro Studies	1 or 2 IRMO	Inter-implant Distance (mm)	Angulation	Initial and Final Number and Type of Cycles	Cross-Head Speed (mm/min)	Medium	Attachment Systems/Retentive Device	Implant Angulation α (°)	Retention Force (N)		Retention Loss (%)
									Initial	Final	
Choi et Jeong, 2018	2	22	Distal	1 400,000 CC & 1080 IRC	50	Deionized water	CM Loc®/Blue (high)	0	44.07 ± 3.07	43.80 ± 2.45	0.52 ± 1.92
								10	45.73 ± 4.29	39.44 ± 8.23	14.69 ± 11.22
Manie wicz et al., 2020	2	20	Mesial	1 10,000 IRC	nc	Artificial saliva	CM Loc®/Red (light)	0	81.8 ± 18.5	49.2 ± 12.6	39.85
								10	47.1 ± 8.6	42.4 ± 13.5	9.99
								20	47.4 ± 8.9	35.4 ± 9.6	25.32
								30	44.4 ± 10.8	41.2 ± 14.8	7.21
							Novaloc®/Yellow	0	57.7 ± 31.0	59.4 ± 16.0	−2.95
								10	41.8 ± 14.8	54.4 ± 15.8	−30.14
								20	48.9 ± 13.9	52.6 ± 8.4	−7.57
								30	76.6 ± 44.5	47.7 ± 18.6	−37.73
							Locator R-Tx®/Pink (medium)	0	75.5 ± 24.9	60.0 ± 19.6	20.53
								10	66.3 ± 16.9	45.5 ± 11.9	31.37
								20	62.3 ± 22.1	33.6 ± 11.4	46.07
								30	78.6 ± 33.3	29.9 ± 18.1	61.96
Yilmaz et al., 2020	2	nc	Distal	1 1440 IRC	50	nc	Locator®/Pink	0/0	13.6	10.0	26.5
								0/30	18.3	12.8	30.0
								30/30	50.2	21.7	56.8
							Locator R-Tx®/Pink	0/0	20.1	14.0	30.3
								0/30	17.5	10.6	39.4
								30/30	33.3	20.0	39.9
Yang et al., 2011	1		nc	1 IRC	60	nc	Dal-ro®/Gold alloy strip	0	6.48 ± 0.34		
								15	6.25 ± 0.2		
								30	5.76 ± 0.16		
								45	4.75 ± 0.92		
							Locator®/Blue	0	15.36 ± 1.4		
								15	14.67 ± 0.74		
								30	13.3 ± 1.7		
								45	6.58 ± 0.34		
Sultana et al., 2017	2	22	Distal	10 10,000 IRC	50	Dry condition	Ball Dentsply/plastic Red Clix®	0	56.2 ± 6.12	46.0 ± 4.74	18.1
								20	45.7 ± 8.03	40.7 ± 2.88	10.9
							Locator®/Pink	0	108.9 ± 29.78	20.2 ± 5.74	81.5
							Locator®/Green	20	82.3 ± 14.15	17.3 ± 3.73	79.0

For interimplant angulation between 20 to 40 degrees, the Locator® manufacturer recommends using extended RD, which provide similar retentive behavior as standard RD used between 0 and 20 degrees. However, it is important to realize that using standard RD for huge interimplant angulations (60°) generate excessive initial retention force but rapid RD wear, due to the larger undercuts created by implant angulation [10,25,27,35,47,48]. No effect of interimplant angulation was observed up to 40 degrees on CM-Loc®, Locator®, Locator R-Tx® and Novaloc® [30,35].

Concerning BAS, until 30 degrees, implant angulation seems to have little impact on their initial retention and loss of retention [10,19,27,49]. However, some authors reported a reduction in their retention force up to 25% increasing implant angulation from 0 to 30 degrees. Regardless of the implant angulation, their initial retention is significantly

lower than CAS, and their retention loss remains negligible (10 to 18% for BAS vs 80% for CAS) [10,19,27]. When implants are not sufficiently parallel, one study [18] highlights the importance of parallelizing the RD and aligning them with the prosthesis insertion path to guarantee sufficient retention. Indeed, parallel RD on parallel implants and parallel RD on nonparallel implants have no significant difference in retention (20.11 N at 0 degrees, 21.21 N at 10 degrees, or 18.78 N at 15 degrees).

No studies were found on CAS regarding RD angulation, but clinical recommendations consist of aligning them with the insertion path.

In IRMO, as implants are positioned in the interforaminal or intercanine area, the consensus establishes that the interimplant distance must range between 15 and 30 mm (Figure 5). According to anatomic limitations and implant space requirements, the mean distance is 22.88 mm [14], and no significant impact was found on the prosthetic construction using different distances (15 mm [13], 20 mm [18,22], or 22 mm [10,32,47,48]). Two in vitro studies [14,33] observed retention sufficient for clinical use for CAS and BAS for different interimplant distances covering the recommended range. Therefore, Practitioners can determine implant position according to the clinical situation without affecting prosthesis retention.

3.4. Influence of Experimental Conditions on Retention, Wear and Maintenance of AS

Several experimental conditions can affect retention and wear observed in in vitro studies. Indeed, the use of a real denture or simulated denture blocks, the dry or wet environmental conditions, the dislodgement speed, the loading conditions, and the characteristics of the testing machine (precision, sensitivity, margin of error) could impact the obtained results.

Although mechanical stress is considered to be the main factor in wear and retention loss of AS, their varied and humid environments (saliva, cleansing products, mouthwashes) have been studied and show little impact on AS retention and wear (Table 5 [22,26,40,50,51]. The main components of several brands of denture cleaners are sodium bicarbonate, sodium perborate, potassium monosulfate, citric acid and ETDA, and only a discoloration was observed on polymer RD with NaOCl solution [26]. Moreover, NaOCl and sodium bicarbonate significantly affect the retention of Locator® after 6-month [26,40,50] and after 12-month immersion time [26,50,51]. The only conclusion that can be drawn is not to immerse AS, especially those composed of polymer RD, in highly reactive chemical solutions (NaOCl) for a long time and to rinse them well after use. Thus, the practitioner should advise patients on the daily maintenance of their prostheses. Prosthesis immersion should be limited to a few hours per week in an appropriate cleansing solution; a regular cleaning using a toothbrush and mild soap after each meal is sufficient and cost-effective.

All studies summarized in Tables 1 and 3 show variable experimental conditions to simulate in vitro wear of a prosthesis and thus to measure the wear and retention loss expected clinically over time. Most studies [10,16,21,40–42] used IRC, one study [13] considered CC, and another one [27] a combination of both cycles. Indeed, the observed wear depends on the chosen fatigue cycle applied to any AS. These cycles applied in vitro are idealized and cannot perfectly represent the complex mechanical loading of an AS in the oral cavity, such as overdenture rotations, excentric chewing, or tilting of the prosthesis before disinsertion. However, all studies show a correlation in the increase in retention loss, wear, and maintenance with the number of cycles and consequently with the time of clinical use. In addition, the cyclic dislodgement rate (cycles/min) could affect the measurement of retention and wear, especially for polymer RDs that exhibit viscoelastic, strain-rate sensitive mechanical behavior. After a dislodging cycle, these materials require time to return to their original shape. The stress magnitude induced in the RD during dislodgment—and thus the retention force—also depends on the disinsertion speed. Most in vitro studies have used a dislodgement rate of 10 cycles/min [21,27,42,47,48] but it can vary between 6 [11] and 40 [14] cycles/min. It has been reported that, the retention force of the Locator® does

not depend on the rate up to 20 cycles/min but decreases significantly at higher speeds (40 cycles/min) [14].

Table 5. Effects of denture cleansing solutions on the initial retention (N) and the retention loss (%) of Locator® attachment system.

In Vitro Studies 1 or 2-IRMO	Cross-Head Speed (mm/min)	Immersion Time, Number and Type of Cycles	RD	Tap Water	Artificial Saliva	NaCl 0.9%	Cool Mint Listerine	NaOCl 6.15%	Aktident	Efferdent	Protefix	Corega	Polident	Polident Overnight
						Sodium Chloride	Menthol Derivatives	Sodium Hypochlorite	Sodium Bicarbonate	Sodium Bicarbonate, Perborate, or Percarbonate, Sodium Carbonate, Potassium Monopersulfate, Citric Acid, EDTA ...				
Ayyıldız et al., 2020 2-IRMO	2	12 M 1 IRC	Blue	41.1 ± 3.9 N				33.3 ± 4.7 N			44.3 ± 4.1 N	52.5 ± 5.9 N		
	50		Pink	58.7 ± 6.5 N				39.7 ± 3.8 N			58.5 ± 4.3 N	58.3 ± 6.8 N		
			White	76.7 ± 8.4 N				52.3 ± 8.5 N			89.0 ± 8.7 N	93.7 ± 5.8 N		
Kürkcüoglu et al., 2016 1-IRM0	50	6 M 12 IRC	Blue	22.1 ± 1.2 N				10.4 ± 3.6 N	7.7 ± 2.2 N		13.8 ± 1.5 N			
			Pink	27.3 ± 2.2 N				29.2 ± 3.3 N	25.5 ± 1.5 N		27.6 ± 1.6 N			
			White	36.7 ± 4.0 N				38.3 ± 1.8 N	23.5 ± 2.5 N		33.6 ± 2.7 N			
Nguyen et al., 2010 2-IRMO	50	6 M 1 IRC	Pink	45.3 ± 3.5 N			51.1 ± 5.3 N	7.8 ± 2.5 N		40.8 ± 2.6 N			45.0 ± 2.3 N	45.0 ± 5.2 N
Srinivasan et al., 2016 2-IRMO	120	10 IRC 10,000 IRC	Blue		35.6 ± 7.5 N 29.8 ± 11.1 N	43.3 ± 16.0 N 37.5 ± 11.9 N								
You et al., 2011 1-IRMO	50	6 M 1 IRC 548 IRC	Pink	22.2 ± 2.3 N 10.5 ± 2.9 N 53 ±12% *			22.3 ± 3.1 N 15.8 ± 4.7 N 29 ± 9% *	12.6 ± 1.5 N 7.3 ± 1.0 N 42 ± 11% *		21.5 ± 1.5 N 11.0 ± 2.2 N 49 ± 9% *				21.8 ± 2.4 N 14.4 ± 3.6 N 34 ± 18% *

* Statistically significant retention loss. Abbreviations: CC, chewing cycles; IRC, insertion–removal cycles; M, months; RD, retention device.

Some authors have observed variations in the retention force within a range of identical attachments [42], as well as differences in size or composition between different batches of the same product [18]. These variations could be related to discrepancies during the manufacturing process and are therefore not controllable or predictable by dental practitioners.

3.5. Limitations

This SR aims to compare the most common BAS and CAS used for 1 or 2-IRMO to assist the practitioner in making reasoned clinical choices. We consider that initial retention and prosthodontic maintenance related to wear and retention loss are critical parameters for the final decision. Thus, the PICO question comprises 5 different outcomes (Initial retention, retention after clinical use, retention loss, wear, maintenance), all related but rarely evaluated in a single clinical or in vitro study. Both types of studies were included in this SR to explain the need for maintenance observed clinically by wear and retention loss mostly observed in vitro. Selected studies present substantial variability in their designs, with numerous parameters concerned:

(i) prosthetic parameters (real or artificial denture, prosthetic design, implant number, interimplant distance, and angulation between implants or between implants and AS),

(ii) in vitro experimental parameters (environment, loading conditions, and sample characteristics),
(iii) clinical conditions in patient studies (bone loss, type of prosthetic construction on the opposing arch, dental occlusion, masticatory forces, prosthetic hygiene, and regular dental aftercare visits after setting denture).

The heterogeneity of reported data also induces missing information in summary tables and limits the quality of evidence of this SR, direct comparison between results being difficult. No meta-analysis could be performed given the low confidence expected due to the lack of standardization of the selected studies.

Additionally, the quality of clinical studies has been assessed as low using RoB 2 criteria, with 7/14 studies at high and 3/14 at moderate risk of bias. In particular, they present a high (4) or moderate (9) risk for other biases summarized in Section 2.6, explicitly introduced for their significance in our SR question (including follow-up, maxillary status, control group and inclusion criteria). The use of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to assess the certainty of evidence from clinical trials could not be performed secondary to the inability to conduct a meta-analysis. To compensate for their low quality of evidence, clinical results were systematically compared with in vitro results when possible. The quality of in vitro studies, assessed with adapted Rob 2 criteria, appears acceptable, with 22/31 studies at low and 9/31 at unclear risk of bias. However, it should be noted that data heterogeneity was substantial, mainly due to protocol variability, especially regarding the control of implant position and insertion/disinsertion axis orientation.

Finally, the studies selected could not fully address the SR question, but they highlighted trends supported by both in vitro and clinical studies. Every identified contradictory result was explained by further analysis of the study design and its bias. The following conclusion summarizes the significant findings, presents guidelines to improve in vitro studies on AS, and clinical recommendations for practitioners.

4. Conclusions

Given the difference in the interlocking mechanisms, the variability of the studies procedures and the lack of standardized technical protocols, a direct comparison of the different AS remains impossible to determine the best AS in 1 or 2-IRMO. BAS remain the most evaluated AS in the literature due to their anteriority, whereas Locator® is now the most used. According to the objectives of this SR, three conclusions can emerge from the studies analyzed.

First, the initial retention forces of CAS are higher than those of BAS, but their resistance to fatigue (retention stability) is much lower, related to the nylon RD wear. After a certain amount of IRC and/or CC, the retention force provided by the Locator® could become lower than the retention force of BAS, but the time threshold remains difficult to determine.

Secondly, implant abutments in each system are barely affected by wear, unlike the RD that show significant plastic deformation, especially in the central core of CAS (Locator®). In contrast, the metallic lamellae RD of BAS present relatively moderate wear at the base and discreet deformation at the top.

Thirdly, the retention loss is correlated to the wear of each RD and justifies regular maintenance, especially during the first year, leading to RD activation (BAS) or replacement (CAS), according to the AS. No significant difference was found in the overall maintenance incidence rate of each RD. Each practitioner will thus choose a system according to its patient needs and clinical situation. BAS initial retention is less effective but more durable than CAS, whereas CAS are more retentive but require a regular change of their RD to maintain their retention superiority.

For in vitro studies, the following guidelines can be proposed to improve their repeatability and enable comparison between them. To characterize the retention of an AS in standard conditions, repeated measures on a single AS should be preferred. The tested AS

must be identified: abutment, chosen retentive device, matrix housing. Blocks containing male and female parts should be carefully manufactured to ensure parallelism (or the required angulation) between the AS axes and the testing machine. Force measurements should be performed with an appropriate load cell (100–500 N), with a dislodging speed (50 mm/min), and in a solution (artificial saliva) representative of the clinical use. Preliminary tests should be performed to set the pre-load value necessary to ensure complete interlocking of male and female parts before dislodgment, especially for polymeric RD. A relaxation time can be added for polymer RD presenting a viscoelastic behavior (Nylon) to let it recover its initial shape. Initial retention should be evaluated as the mean of the 10 first cycles. For fatigue testing, retention force should be reported at specified regular intervals (e.g., 1–10–100–1000–5000–10,000) to reflect the progressive retention loss observed clinically.

Based on this SR, clinical recommendations for AS in IRMO can be made:

For all AS, practitioners can localize their implant according to the clinical situation but should avoid interimplant angulation, especially in the sagittal plane. They need to use dedicated instruments for the maintenance of the RD and favor polymeric RD (CAS) or precious alloy RD (BAS) versus titanium abutments to limit wear of the AS. Recommendations have to be explained to the patient concerning the cleansing and maintenance of prostheses, avoiding aggressive solutions.

CAS should be preferred: (i) in situations of low vertical prosthetic space, although they have a larger cross-section compared to 2.25 mm standard diameter for BAS, (ii) when initial retention is required to be higher, (e.g., in lingual parafunction, bruxism, or in case of a poor surface of sustentation), and (iii) if the axis of the implant is different from the insertion axis of the prosthesis over 30° with the use of extended RD adapted to high angulations. The standard 2.25 mm diameter BAS should be preferred: (i) in situations with low bone width and (ii) if the required retention is not strong but stable over time (e.g., if the patient has difficulty making frequent visits to the practitioner or is disabled). They can be used until 30° angulation in accordance with the insertion pathway.

These recommendations should be seen in the context of other essential aspects such as: (i) the implementation time, and the mastering of the system by the practitioner and the prosthetist, (ii) the easy placement and removal of the prosthesis by the patient, (iii) the inevitable frequent adjustments and repairs, and (iv) the patient compliance for recall.

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Abbreviations

AS	attachment system
BAS	ball attachment systems
CAS	cylindrical attachment systems
CC	chewing cycle
IRC	Insertion–removal cycle
IRMO	implant-retained mandibular overdenture
PEEK	polyetheretherketone
RD	retention device
RoB	risk of bias
SR	systematic review

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Chapitre 2 : Evaluation de la rétention initiale

Introduction

L'analyse de la littérature [7] effectuée dans la première partie nous a permis de nous rendre compte de l'absence de protocole technique standardisé entre les études évaluant la rétention initiale des SAB comme le Ball System et des SAC tels que le Locator R-Tx® et le Novaloc® associés à la PACM retenue sur 1 ou 2 implants, ce qui rend impossible une comparaison adéquate entre les études.

Les objectifs de ce chapitre sont :

1) Construire un protocole expérimental applicable à plusieurs SA de façon reproductible tout en limitant le nombre de biais. On s'attachera particulièrement au contrôle de l'orientation de l'implant par rapport à l'axe d'insertion/désinsertion de la prothèse.

2) Appliquer et caractériser la fiabilité de ce protocole sur 3 SA : un SAB (Ball System) et deux SAC (Locator R-Tx® et Novaloc®).

3) Evaluer la rétention initiale de ces 3 SA et réaliser une analyse statistique pour comparer entre eux (a) les différents DR au sein d'un même SA et (b) les différents SA au sein de groupes de rétention similaire (faible, moyenne et élevée).

Matériels et Méthodes

La rétention initiale est définie comme la moyenne de la force maximale de désinsertion (en N) après 10 cycles d'insertion-désinsertion (CID) entre la partie mâle vissée sur l'implant inséré dans un bloc de polyméthacrylate de méthyle (PMMA) – simulant l'os – et la partie femelle assemblée via une résine autopolymérisable au bloc de PMMA – simulant la PACM. Pour le SAB (Tableau 1), le DR étant activable, 3 degrés d'activation ont été évalués. Pour les SAC (Tableau 1), toute la gamme de DR de chaque système a été considérée. Pour chaque DR ou degré d'activation, 8 échantillons ont été inclus dans l'étude pour détecter une différence de l'ordre de 5 N avec une puissance statistique de 0.8 et un niveau de significativité de 0.05. La calibration des DR du SAB

est contrôlée sur des images acquises grâce à une loupe binoculaire. L'angulation des SAC est vérifiée à partir d'acquisitions CT-scan de haute résolution. Le mouvement d'insertion-désinsertion est vertical, uni-axial, rapide (60 mm/min), dirigé selon le grand axe de l'implant. L'expérimentation s'effectue à température ambiante en conditions sèches.

	Locator R-Tx®	**Novaloc®**	**Ball System**
Nombre d'implants	4	4	4
Nombre de piliers implantaires	4	4	4
Nombre de boitiers femelles	4	4	4
Dispositifs de rétention	LG (gray) (n = 8) LB (blue) (n = 8) LP (pink) (n = 8) LW (white) (n = 8)	NR (red) (n = 8) NW (white) (n = 8) NY (yellow) (n = 8) NG (green) (n = 8) NB (blue) (n = 8) NK (black) (n = 8)	B_{low} (n = 8) B_{med} (n = 8) B_{max} (n = 8)

Tableau 1 : Nombre d'échantillons des systèmes d'attachements testés.

Résultats et Discussion

Nous avons fait le choix de simuler une PACM retenue sur 1 implant comme dans plusieurs études [13-16], même si cliniquement la PACM retenue sur 2 implants reste la norme. Cette stratégie permet d'obtenir des valeurs de rétention initiale en supprimant les biais liés à l'utilisation de plusieurs implants comme leur nombre, l'angulation ou la distance inter-implantaire et permet de comparer plus facilement les données obtenues entre elles, et avec celles des fabricants. L'usinage des blocs de PMMA a permis de limiter l'angulation implantaire sous le seuil toléré en clinique (3°) et d'accéder à une répétabilité satisfaisante des mesures. Le contrôle de la calibration du Ball System a montré une variabilité dans le réglage manuel probablement lié à l'incertitude dans la position correspondant à l'activation maximale du système (Cf. Chapitre 4, Paragraphe 4.1.1).

Les plages de rétention initiale sont similaires entre le Ball System (6,8 ±3,0N à 19,9 ±4,0N) et le Novaloc® (2,0 ±0,5N à 18,9 ±1,4N) tandis que celle du Locator R-Tx® est plus étendue (3,3 ±5,0N à 60,2 ±5,9N). La majorité des DR génèrent une force supérieure à 5N, valeur seuil supposée assurer la satisfaction des patients (la littérature ne précise pas le nombre d'implants concerné par la PACM). La rétention intiale mesurée pour le Novaloc® suit la même tendance mais est plus faible de 10 à 30% par rapport aux données du fabricant tandis que le Ball System est conforme aux indications du fabricant. Par rapport au Locator® classique, le Locator R-Tx® offre une gamme de rétention plus large tandis que le Novaloc® présente une gamme similaire mais avec une meilleure répétabilité pour chaque DR.

Dans la comparaison intra-système, les 4 DR du Locator R-Tx® montrent une différence statistiquement significative basée sur la rétention initiale : LG/ 3,2N ; LB/ 22,1N ; LP/ 35,9N et LW/ 60,2N. De même le Novaloc® présente une différence statistiquement significative entre tous ses DR, sauf entre les deux plus rétentifs (NB et NK) : NR/ 1,9 N ; NW/ 6,4 N ; NY/ 9,9N ; NG/ 13,7N ; NB/ 18,5N ; NK/ 18,8 N. Pour le Ball System, la différence est significative entre B_{low} (6,7N) et les deux autres groupes, B_{med} (13,7N) et B_{max} (19,8N).

Pour chaque groupe de rétention (faible, moyenne ou élevée), le Locator R-Tx® présente le DR qui a la rétention initiale la plus élevée et statistiquement différente des autres qui présentent une rétention similaire entre eux.

Conclusion

A partir du protocole expérimental standardisé mis en place pour effectuer la simulation d'une PACM retenue sur 1 implant, nous avons effectué une comparaison intra- et inter-système entre les 3 SA. La rétention initiale est significativement plus élevée pour le Locator R-Tx® que pour le Ball System et le Novaloc®. Les valeurs de rétention obtenues semblent suffisantes et dans la limite de rétention acceptée par le patient pour une PACM retenue sur 1 implant, sauf pour les DR Novaloc® Red et Locator R-Tx® Gray.

Perspectives

Pour garantir le succès thérapeutique, il est indispensable de maintenir un certain niveau de rétention au cours du temps. Ainsi, des études complémentaires sont nécessaires pour analyser l'évolution de la rétention de ces 3 SA au cours du temps, paramètre clinique majeur permettant d'anticiper les besoins de maintenance. L'utilisation de plusieurs implants étant la norme en clinique, il sera également intéressant d'étudier dans un second temps l'influence de l'angulation implantaire, du nombre d'implants, de l'angulation inter-implantaire, de l'angulation du DR rapport à l'axe d'insertion sur la force de rétention.

Article 2

Les travaux de cette partie sont détaillés dans l'article ci-dessous, re-soumis en février 2023 dans *Journal of Prosthodonctics* après corrections majeures, puis en avril 2023 après corrections mineures, et accepté le 25 juin 2023.

Initial retention force of three attachment systems for implant retained-mandibular overdentures: An in vitro study.

Running Head: 1-IRMO BAS vs CAS: in vitro initial retention

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ABSTRACT

Objective. To evaluate and compare the initial retention force of three resilient unsplinted attachment systems for implant-retained mandibular overdentures: two cylindrical attachment systems (Locator R-Tx® and Novaloc®), and one ball attachment system (Ball System).

Materials and methods. For each attachment system, initial retention is measured as the average of the maximal dislodging forces during 10 insertion-removal cycles. For the Ball System, 3 activation degrees of the matrix are included whereas 4 and 6 color-coded retention devices for the Locator R-Tx® and the Novaloc® respectively to represent the complete regular retention devices panel. For each retention device or activation degree, 8 samples are tested.

Results. The initial retention range is similar between the Ball System (7.7 ±3.4 N – 19.9 ±4.6 N) and the Novaloc® (2.0 ±0.5 N – 18.9 ±1.4 N) and broader for the Locator R-Tx® (3.3 ±5.0 N – 60.2 ±6.0 N). In each attachment system, each retention device has its initial retention significantly different from the others, except for the two most retentive Novaloc® ones. Retention devices were also classified according to their initial retention (low, medium, and maximum). In each retention group, the Novaloc® and the Ball System provide similar retention values lower than the Locator R-Tx®.

Conclusion. Most of the retention devices provide an initial retention force over 5 N for all the three attachment systems. The Locator R-Tx® has the most comprehensive range, and the Novaloc® seems to provide the most reproducible values, unlike the Ball System due to the activation required by the operator.

Keywords. Initial retention force, ball and cylindrical attachment systems, implant-retained mandibular overdenture.

INTRODUCTION

There is a wide variety of implant-supported prosthodontic designs for treating the edentulous mandible, depending on the number of implants and the connection between dentures and implants. The implant-retained mandibular overdenture (IRMO) is stabilized on 1 to 4 implants inserted in the interforaminal area.[1,2] According to the McGill consensus established in 2002,[3] and to the updated York Consensus conference statement,[4] an IRMO stabilized on two implants is the standard of care. The main factors associated with the superior effectiveness of IRMO over conventional overdentures are retention and stability provided by the attachment systems (AS) connected to the implants and the denture base.[5] In addition, IRMO are more cost-effective in the long-term[6] and significantly improve i) masticatory ability, ii) patient satisfaction,[7-10] iii) their quality of life,[11] and iv) the preservation of the residual ridge height.[6,12]

In a meta-analysis, Payne et al. (2018)[1] concluded that for 1 to 4-IRMO, there is insufficient evidence to determine the relative effectiveness of different AS on costs, patient satisfaction or preference, prosthodontic success, or maintenance. Various parameters must be considered for a rational clinical choice: i) the target immediate and long-term retention, ii) the advantages and disadvantages of each AS,[13] iii) the individual clinical situation (anatomy, prosthetic space),[14] iv) the patient expectations,[14,15] v) the angulation of the implants or the AS,[7] vi) the occlusion and the load distribution on the implants, the mucosa and the ridge,[16] vii) the implementation time at the chairside and in the laboratory,[6] viii) the maintenance frequency,[17] and ix) the patient compliance for recall.[12] However, the primary criterion to select an appropriate AS is its required retention.[12,16] Denture retention is defined as the maximum force developed along the insertion direction of the denture until dislodgment from its mucosal and or implant-bearing surfaces.[10,16,18] To ensure a satisfactory retention level, some authors suggested that 5-7 N are sufficient for IRMO[6,12,19] but without specifying the number of implants, whereas other investigators proposed 10 N[20] or 20 N for 2-IRMO.[21,22] Usually, the greater the retention, the more satisfied patients.[17]

Most of the clinically used and investigated AS are i) the ball attachment systems (BAS),[1] as the Ball System (Nobel Biocare AB, Göteborg, Sweden), and ii) the cylindrical attachment systems (CAS) such as Locator® (Zest Anchors, Escondido, CA, USA), and more recently Locator R-Tx® (Zest Anchors, Escondido, CA, USA) and Novaloc® (Straumann AG, Basel, Switzerland), with new design features

promoted by the manufacturers to improve initial retention. BAS retention varies between 2 and 16 N for 1-IRMO or between 10.6 N and 56.2 N for 2-IRMO.[5] A limited number of studies have examined the Novaloc® and the Locator R-Tx® AS, focused on one RD only (Novaloc® yellow and Locator R-Tx® Pink) and presented contradictory data, mainly due to the differences in their protocols, which were not sufficiently detailed.[23-25] To our knowledge, no study has assessed and compared the initial retention of the full range of color-coded RD of the Locator R-Tx® and the Novaloc®, with different activation levels of the reference for the Ball System.

Our team highlighted in a systematic review[5] the need for more standardization of the protocols measuring AS retention, especially regarding implant angulation, in order to facilitate comparison between studies. Clinical studies have shown that without a surgical guide, a perfect alignment cannot be reached so that experienced practitioners place two implants with an interimplant angulation varying between 1 to 7.5 degrees[11] and that interimplant angulation above 6 degrees requires a significantly higher number of denture adjustments.[9] Because of the spherical shape of their abutment, BAS are little affected by interimplant angulation, the friction surfaces between male and female parts being identical for low angles (<30°).[9,13] For CAS, in vitro studies have confirmed that interimplant angulation significantly affected its initial retention[8,10,16,18,25] even if no clear tendency between angulation and retention could be highlighted because of the complexity of the interactions between male and female parts. Angulation of the AS should be carefully controlled to limit this bias.

The purpose of the present in vitro study was to design a reliable protocol for 1-IRMO, to evaluate and compare the initial retention force of the different color-coded RD of the Locator R-Tx® and the Novaloc®, and of the three activation degrees of the Ball System.

MATERIALS AND METHODS

Attachment systems

Three different unsplinted AS were included in the study, one Ball System associated with 3 levels of retention and two CAS, Locator R-Tx® and Novaloc®, associated with their full range of regular RD.

Height samples of each color-coded RD were included: Locator R-Tx® grey (LG), blue (LB), pink (LP), white (LW) and Novaloc® red (NR), white (NW), yellow (NY), green (NG), blue (NB) and black (NK). Four assemblies of each AS composed of an implant, an abutment and a matrix housing, were used for all tests. The Locator R-Tx® assembly was composed of an implant with an internal conical connection associated with a straight abutment with 4 mm gingival height and a cylindrical stainless-steel female case (Nobel Parallel™ Conical Connection Regular Platform, 4.3×10 mm, Nobel Biocare AB, Göteborg, Sweden). The Novaloc® assembly was composed of an implant associated with a straight abutment with 4 mm gingival height and a cylindrical titanium female case (bone level Regular Connect, SLA® surface, Loxim®, 4.1×10 mm, Straumann AG, Basel, Switzerland). For all RD, the 8 samples were randomly distributed over these 4 assemblies, meaning 2 samples each. The RD was inserted and removed in its metal housing using appropriate tools.

For the Ball System, 8 samples of 3 retention levels (maximum, medium, and low) were included in the study. All lamellae were first activated to maximal retention by rotating them to their utmost position. The maximum retention group (B_{max}) corresponded to this initial position. A half turn then deactivated lamellae for the medium retention group (B_{med}) and one turn for the low retention group (B_{low}). Four assemblies composed of an implant (Brånemark System® Mk III Groovy Regular Platform, 4.0×10 mm, external connection, Nobel Biocare AB, Göteborg, Sweden) and a straight ball abutment were used for all tests. The 24 samples of lamellae were randomly distributed and calibrated in the three retention level groups (B_{max}, B_{med}, B_{low}) and used successively for these 4 assemblies, each one receiving 2 samples of each level group.

Fabrication of the models

An experimental set-up simulating a clinical 1-IRMO situation was carried out (Fig. 1). Each implant was screwed in a machined polymethyl methacrylate (PMMA) block (35×35×20 mm^3) representing mandibular bone using an appropriate implant holder, screwdriver, and torque control device set at 35 N/cm. The block was pre-drilled at a diameter 0.5 mm smaller than the implant diameter to ensure implant fixation close to osseointegration and an implant axis perpendicular to the lower plane of the block, in

contact with the machine's frame, thus guaranteeing alignment between implant and insertion/removal axes. According to the manufacturer, each abutment was tightened on the corresponding implant with a torque of 15 N/cm. A 3 mm deep cylindrical socket was machined in the antagonist PMMA cylinder block (40mm height, Ø 16mm) representing the overdenture, at a diameter 0.4 to 0.5 mm smaller than the matrix housing external diameter to pre-position the housing and limit the angulation between insertion/removal and housing axes. Each matrix housing was embedded using auto-polymerizing acrylic resin (Biocryl®, Scheu Dental GmbH) in the socket, taking care to prevent excess material from flowing into the RD space.

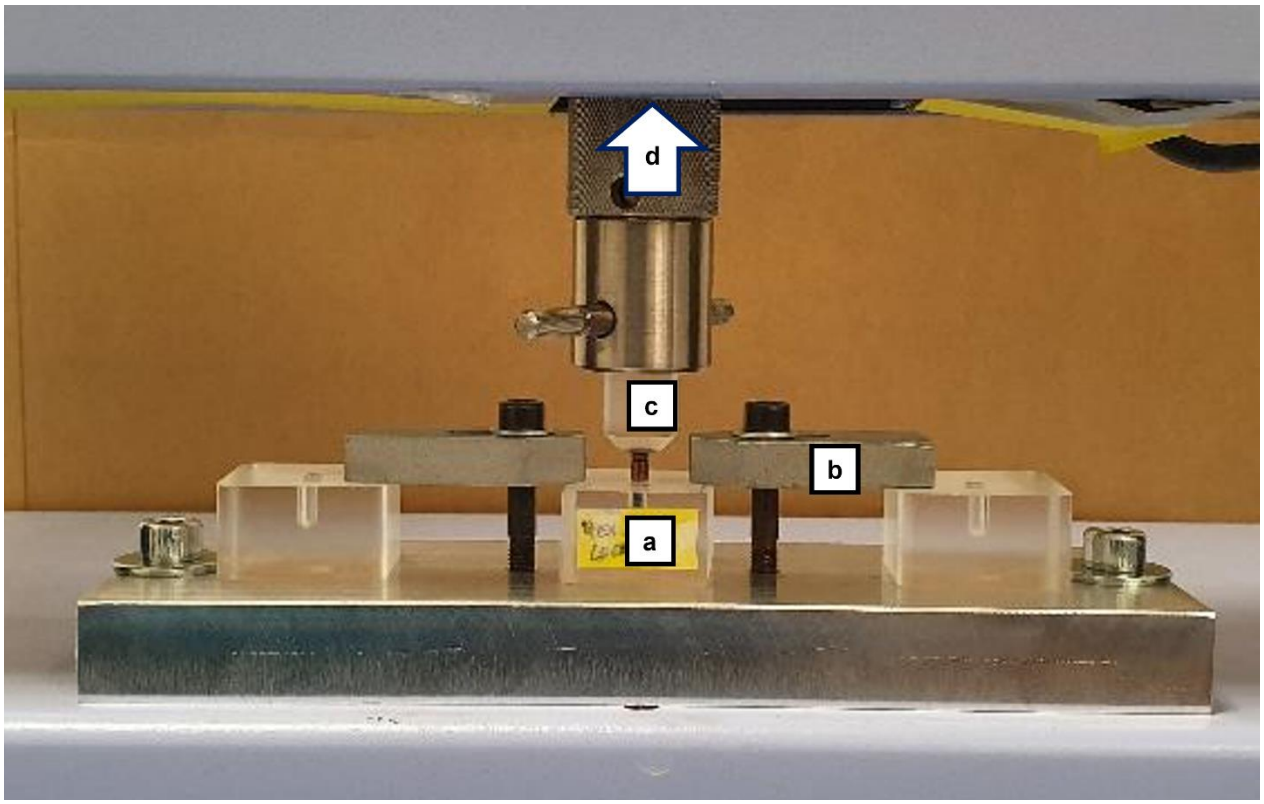

Fig. 1: Experimental set-up. (a) Lower resin block with implant and abutment, (b) Mounting flange, (c) Upper resin block with two-piece matrix, (d) Load cell.

Control of the models

To control BAS calibration, the width of the lamellae principal slit was measured on their inner surface with ImageJ® software, using ×50 magnification binocular images (Fig. 2a). Angulation between insertion/removal and matrix housing axes was limited to a maximum of 8° by the designed socket and was not investigated because of its negligible impact on initial retention.

Conversely, since even small angulations have an impact on CAS retention, this one was measured for each assembly from high-resolution CT-scan acquisitions (Quantum FX, Perkin Elmer, voxel size 40×40×40 μm^3) of the cylinder block associated with the matrix housing (Fig. 2b). After segmentation, the 3D external surfaces (STL files) of the cylinder and the matrix housing were reconstructed using marching cubes algorithms using CTAn software (CTAn, v 1.20, Bruker) and imported into GOM Inspect software (Gom Inspect v 8, Gom). A perfect cylinder was fitted on the cylinder surface (Fig. 2b, green cylinder), and a perfect plane on the bottom of the matrix housing (Fig. 2b, purple plane). The angulation between the normal to the plane (Fig. 2b, purple line) and the cylinder axis (Fig. 2b, green line) was measured to estimate the angulation between the insertion axis and matrix housing.

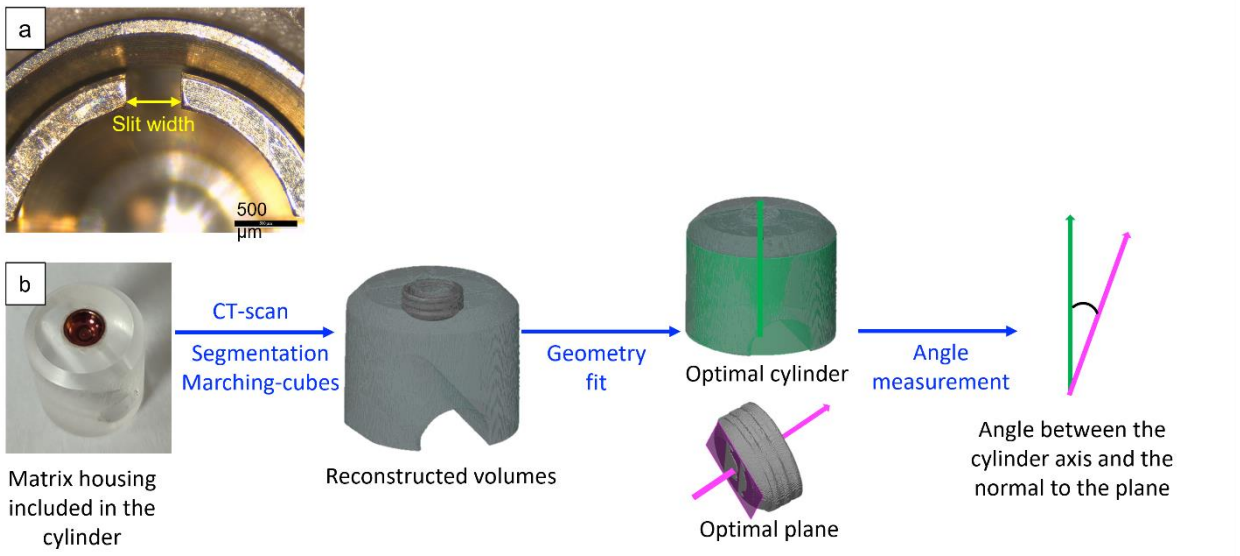

Fig. 2: Control of the models. Measurement of (a) the RD main slit width from binocular images for BAS and (b), the angulation between the insertion axis and matrix housing from CT-scan acquisitions for CAS.

Mechanical testing

Insertion-removal cycles (IRC) were performed in a dry environment using a universal testing machine (Shimadzu Autograph AGS-X) equipped with a 100 N load cell (Fig. 1). Before the first cycle, the two blocks were manually clipped by the operator and fixed to the upper jig. The assembly was slowly downed until the lower block contacted the machine; crosshead displacement was adjusted to limit the retentive and compressive forces under 0.5 N when fastening the lower block on the machine's frame. The first cycle consisted of a vertical displacement until the separation of the AS at a crosshead speed of 60 mm/min, similar to most in vitro studies[7,8,13,19,22] and considered as the speed of IRMO removal by the patient. After this first IRC, the crosshead was manually downed until a compressive preload of 15 N (except for the Ball System, where no preload was applied to avoid plastic damage) was reached to ensure complete interlocking of male and female parts at every following cycle. From this reference position, each sample was subjected to 9 consecutive IRC that consisted of vertical up and down displacements of 1.5 mm at a crosshead speed of 60 mm/min, sufficient to obtain the separation of male and female parts at every cycle. Initial retention was considered as the average of the maximal dislodging forces measured during the 10 IRC, similar to most in vitro studies.[9,17,19,22, 26-28]

Statistical analysis

Numerical variables were expressed as the mean ± standard deviation (SD). The statistical analyses were performed using Prism GraphPad software version 7.04. The normality of the distribution was tested with the D'Agostino-Pearson Normality test and Shapiro Wilks Normality test to choose between non-parametric and parametric tests to apply.

The three categories were created depending on the expected retention: lowretention (B_{low}, LG, LB, NW, and NR), medium retention (B_{med}, LP, NG, and NY), and maximum retention (B_{max}, LW, NK, and NB). Within each retention group, the measurements obtained were compared, as well as within each AS. A non-parametric Kruskall-Wallis or a one-way Anova test was applied, followed by a Tukey Test. One RD was considered as the statistical unit. Differences were considered significant at $p < 0.05$.

RESULTS

The BAS main slit width progressively increases when retention decreases: 314 ±22 µm for B_{max}, 370 ±11 µm for B_{med}, and 446 ±10 µm for B_{low} (Fig. 3, Suppl Table 1). As statistical distribution is not normal for B_{med}, Kruskal-Wallis non-parametric test is applied and highlights a difference between B_{low} and B_{max} only. For CAS assemblies, the maximum angle between the upper block axis and the matrix housing is measured at 2.11° for Locator R-Tx® and 2.38° for Novaloc® (Suppl Table 2).

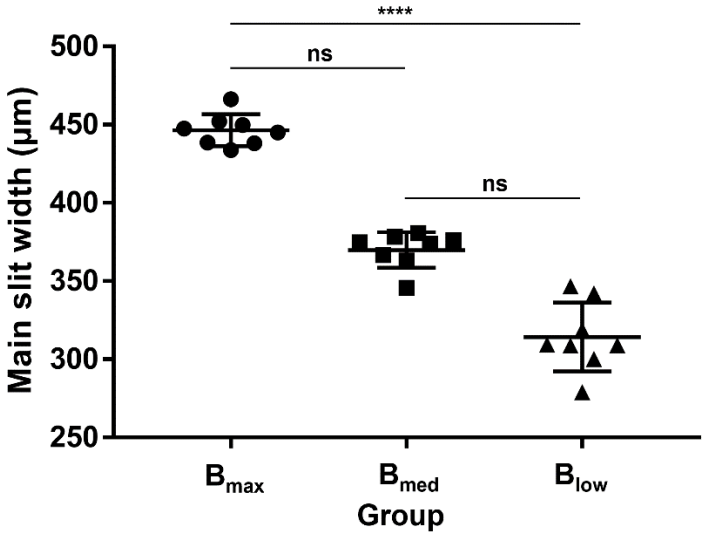

*Fig. 3: Width of the RD main slit for BAS: Kruskall-Wallis test shows a significant statistical difference between B_{low} and B_{max} only (****, p < 0.0001; ns, non-significant difference).*

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Sample 7	Sample 8
B_{max}	318.6	308.8	278.8	346.6	308.7	309.1	300.0	341.9
B_{med}	373.7	375.9	374.7	345.4	380.5	366.5	363.0	378.2
B_{low}	447.3	466.1	433.6	449.7	437.9	438.2	444.9	451.9

Suppl. Table 1: Lamellae main slit width measurement (µm) for each activation level of the Ball System.

	Sample 1	Sample 2	Sample 3	Sample 4	Mean	Standard deviation
Locator R-Tx®	0.7	2.1	0.9	1.5	1.3	0.5
Novaloc®	1.2	0.7	2.3	1.4	1.4	0.6

Suppl. Table 2: Angulation (°) between the insertion axis and matrix housing from CT-scan acquisitions for Locator R-Tx® and Novaloc®.

The initial retention force depends on the selected RD (Table 1, Suppl Table 3). The three AS provide different retention ranges: 2 - 20 N for the Novaloc®, 3 - 60 N for the Locator R-Tx®, and 8 - 20 N for the Ball System with the chosen activation settings (Table 1). The Novaloc® shows highly repeatable initial retention for all its RDs with standard deviations between 0.5 N and 1.4 N. The Ball System shows intermediate standard deviations (2.8 N to 4.6 N), whereas the highest standard deviation is observed for the Locator R-Tx® (5.0 N to 8.9 N).

Regarding initial retention inside each AS (Fig. 4), the Locator R-Tx® shows a statistically significant difference between the 4 RD with 4 distinct mean retention levels: 3.3 N for LG, 22.2 N for LB, 36.0 N for LP, and 60.2 N for LW. For the Novaloc®, there is a statistically significant difference between all RD, except between the most retentive NB and NK RD, providing the following mean retention: 2.0 N for NR, 6.5 N for NW, 10.0 N for NY, 13.7 N for NG, 18.5 N for NB, and 18.9 N for NK (Table 1). For the Ball System, the difference in initial retention is significant between B_{low} and B_{max} only. The mean observed retention levels are 7.7 N for B_{low}, 13.8 N for B_{med}, and 19.9 N for B_{max} (Table 1).

For each retention group (Fig. 5), one Locator R-Tx® RD shows higher retention than the other RD of similar retention: LB (22.2 N) vs LG, NR, NW, and B_{low} (2.0-7.7 N) for lowretention; LP (36.0 N) vs NG, NY, and B_{med} (10.0-13.7 N) for medium retention; and LW (60.2 N) vs NK, NB, and B_{max} (18.5-19.9 N) for maximum retention.

Attachment system		Ball System			Locator R-Tx®				Novaloc®					
Retention device		B_{max}	B_{med}	B_{low}	LW	LP	LB	LG	NK	NB	NG	NY	NW	NR
Manufacturer's retention (N)		15-22	10-15	5-10	High*	Medium*	Low*	Zero*	25.0	20.6	16.1	11.7	7.3	2.9
Retention measured (N)	Minimal	14.5	7.6	2.5	54.0	25.1	15.1	0.0	16.9	17.0	12.2	8.7	5.6	1.2
	Maximal	25.5	16.6	10.8	71.2	47.8	37.0	12.9	20.7	20.9	15.4	12.1	7.4	2.5
	Mean ±SD	19.9 ±4.6	13.8 ±2.8	7.7 ±3.4	60.2 ±6.0	36.0 ±8.9	22.2 ±7.5	3.3 ±5.0	18.9 ±1.4	18.5 ±1.4	13.7 ±1.1	10.0 ±1.2	6.5 ±0.7	2.0 ±0.5

Table 1: Initial retention force of the different RDs of the Ball System, the Locator R-Tx®, and the Novaloc® (, Qualitative data only; SD, standard deviation).*

	Retention device	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Sample 7	Sample 8	Mean	Standard deviation
Ball System	B_{max}	15.2	14.5	18.5	15.3	25.1	23.7	25.5	21.3	19.9	4.6
	B_{med}	14.7	12.2	7.6	14.1	15.6	13.9	16.6	15.6	13.8	2.8
	B_{low}	7.0	2.5	2.5	9.5	10.8	8.3	10.7	10.1	7.7	3.4
Locator R-Tx®	LW	56.7	60.5	59.8	54.0	71.2	66.6	58.3	54.5	60.2	6.0
	LP	32.3	44.4	46.0	25.1	26.8	31.5	34.0	47.8	36.0	8.9
	LB	21.8	22.0	17.2	20.1	29.0	37.0	15.3	15.1	22.2	7.5
	LG	0.0	2.4	0.0	9.1	1.5	0.2	0.0	12.9	3.3	5.0
Novaloc®	NK	20.5	17.7	16.9	19.7	20.7	19.7	17.9	18.0	18.9	1.4
	NB	18.5	17.5	17.0	17.0	20.9	19.9	19.4	17.9	18.5	1.4
	NG	12.4	14.3	13.3	14.9	15.4	13.5	13.8	12.2	13.7	1.1
	NY	8.7	9.7	9.0	10.4	10.9	10.2	12.1	9.0	10.0	1.2
	NW	6.5	7.4	5.7	5.9	6.8	7.0	6.9	5.6	6.5	0.7
	NR	2.5	2.5	1.2	1.7	2.3	2.4	1.8	1.5æ	2.0	0.5

Suppl. Table 3: Initial retention force (N) of each plastic retention device and the activation level of the gold lamellae

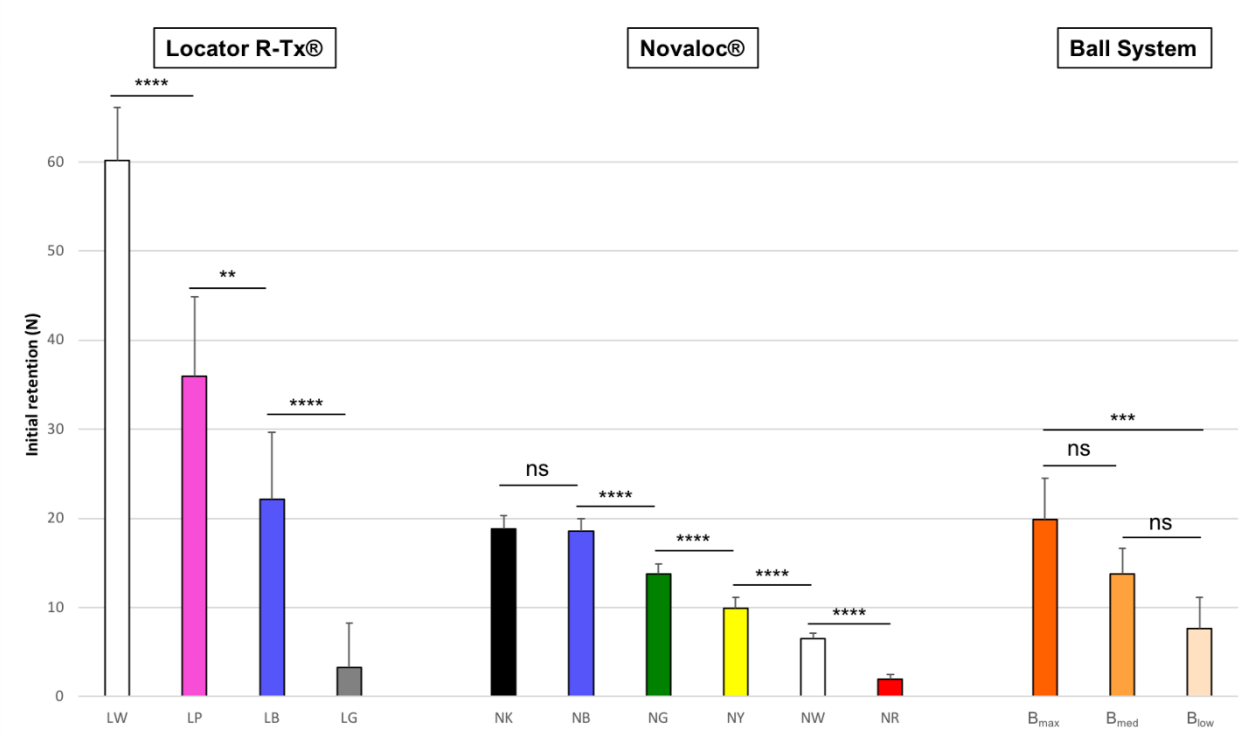

*Fig. 4: Comparison of the initial retention of the different retention devices inside of each attachment system. The difference is significant between all the Locator® RD; between all the Novaloc® RD (except between NK and NB); between B_{low} and B_{max} positions of the Ball System. (**, p <0.01; ***, p < 0.001; ****, p < 0.0001; ns, non-significant difference).*

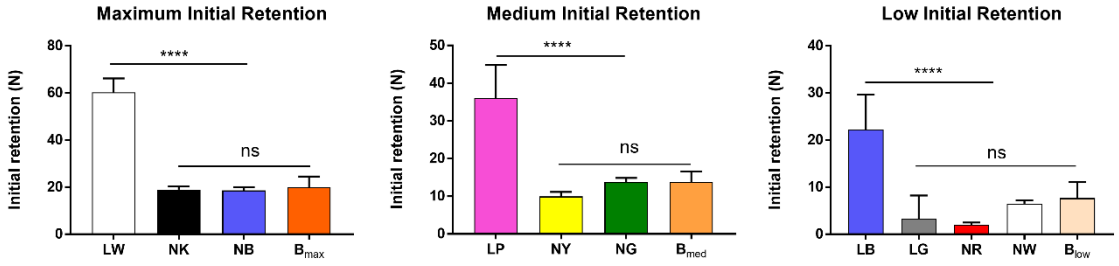

*Fig. 5: Comparison of the initial retention of the different attachment systems inside of each retention group (****, p < 0.0001; ns, non-significant difference). Inside the maximum, medium, and low retention groups, there is a significant difference respectively between LW and the other AS (NK, NB, B_{max}), between LP and the other AS (NG, NY, B_{med}), between LB and the other AS (LG, NR, NW, B_{low}). No statistical differences were found between the others; ns: non-significant.*

DISCUSSION

The purpose of the present study was to underline the difference in the initial retention force of 3 AS through an experimental set-up simulating a clinical 1-IRMO situation inserted in the insertion axis. The 3 investigated AS were selected as the most effective in their category according to our review.[5] In Wakam et al. 2022,[5] guidelines were suggested to improve the repeatability of in vitro studies and enable comparison between them. This study's design is focused on controlling the alignment of the different parts to minimize the bias related to implant angulation. Angulations lower than 3° were reached between the matrix housing and the insertion axis thanks to the blocks' machining and the operator's meticulousness. This value, corresponding to an inter-implant angulation of 6°, was considered clinically as a threshold to limit the need for maintenance and should not impact retention measurements.[9,11] Repeated measures on a single AS were preferred to prosthetic designs with several implants to avoid any retention bias related to implant mispositioning. Types and numbers of cycles to measure initial retention as well as dislodging speed were following other in vitro studies.[17,22,27] The sample size (n=8 per group) was selected by the literature[8,10,17,19,22-24,27,29,30] and to detect a variation in retention of 5.2 N with a statistical power of 0.8 and a significance level of 0.05 for BAS (standard deviation of 3.7 N[22]). All Kruskall-Wallis and one-way Anova tests showed significant differences between analyzed groups.

Standard deviations were expected to reflect this rigorous protocol. The Novaloc® showed standard deviations lower than 2 N, comparable to the interquartile range of 3.3 N measured on a single AS[23] and far below the standard deviation of 31 N on simulated 2-IRMO.[24] This indicates a highly repeatable behavior of the RD during dislodging related to the controlled alignment of the different parts in the loading machine and to the PEEK stiffness that prevents unwanted tilting. The higher standard deviations observed for the Ball System were in accordance with the literature,[13,17] and could partly be explained by the operator-dependent activation procedure. Indeed, the chosen calibration procedure required screwing the lamellae until its maximum retention position, which can be hard to determine. The manual adjustment generated inaccuracies reflected in particular by the significant variations in lamellae slit width of the B_{max} group. The highest standard deviation observed for the Locator R-Tx® was comparable to or below the variability found in the literature.[23,24] Former models of Locator® already presented high variability in

manufacturing similar polyethylene RD.[8-10,17,19,26] Retention variability can also be explained by the authorized movements of the RD in its housing during dislodging. Even if the matrix housing is aligned with the insertion and the abutment axes, the space provided for AS resilience associated with polyethylene flexibility authorizes RD tilting in its housing and generates inappropriate contact.

The repeatability of the measurements related to the low standard deviations, particularly for the Novaloc®, confirmed the rigor of the protocol and its reproducibility (pre-drilled machined resin blocks, positioning of the implant and AS, pre-loading, insertion-removal axis) needed to produce a fair comparison between the considered AS. Although in vitro studies allow standardization of the tests by excluding some clinical conditions (wet environment, chewing strength, presence of mucosa, multiplicity of implants), they present several limitations. In this study, the measured retention considered the AS alone and did not estimate the additional retention provided by soft tissues. Retention was only measured along the chosen insertion axis, with a selected speed that does not represent the actual in vivo non-axial dislodging loading to which the denture base can be subjected.[18] At last, dislodgment tests were conducted in a dry environment, whereas saliva is known to affect retention in vivo and in vitro.[13,19]

Results of this in vitro study have shown that the initial retention force of the Ball System for 1-IRMO, depending on the activated position of the gold RD, agree with the manufacturer's data and other studies on BAS using similar protocols.[13,17]

The initial retention forces of the Novaloc®, depending on the color-coded RD, follow the same trend but are lower by 10 to 30% than the manufacturer data. For the Locator R-Tx®, the measurement is in accordance with the qualitative information given by the manufacturer. Moreover, the Locator R-Tx® give better initial retention than the classic Locator®: 3.84 N - 16.6 N according to available studies, or 6.6 - 22.2 N according to manufacturer data.[5] The Novaloc® provide a similar retention range as the classic Locator® but with less RD variability.

To our knowledge, only one in vitro study characterized and compared the Locator R-Tx® and Novaloc® AS by simulating a 1-IRMO.[23] However, tilting the prosthesis induced by an eccentric force is too different from vertical dislodging to allow a fair comparison with this study. These two AS were also characterized by Maniewicz et al.[24] using a 2-IRMO. As in our study, LP (75.5 ±24.9 N) was found to be more retentive

than NY (57.7 ±31.0 N), and the measured retention in 2-IRMO was at least twice the retention measured on a single AS in this study (LP 36.0 ±8.9 N, NY 10.0 ±1.2 N). However, the difference in retention between both AS was almost three times lower than our measurements. Another in vitro study showed a retention force of 20.1 ±0.1 N for LP using a 2-IRMO.[25] Considering the low value found in this study, we can assume that the two AS included in the prosthesis were not completely interlocked before dislodgement. Even if 1-IRMO configuration allows us to compare our results directly with manufacturer data, a direct comparison with IRMO on multiple implants should be taken with caution because initial retention depends on various parameters (e.g., interimplant angulation, implant spacing, insertion-removal axis), specific to these configurations. Additionally, 1-IRMO configuration allows strict control of the angulation necessary to evaluate appropriately the retention of three AS to help the practitioner make his choice according to his clinical needs. According to Burns, the greater the retention, the more satisfied patients are.[20] The initial retention is often the key parameter for the success of prosthesis integration by the patient, whether for functional reasons (e.g., stability during mastication, phonation, swallowing) or psychological reasons (e.g., fear that the prosthesis will fall out in front of others, or of not being able to remove it) even if retention needs may vary according to many parameters (e.g., the surface of sustentation, parafunctions, age, dexterity, saliva quality, stability needs, availability to allow adequate maintenance).

Results show that in 1-IRMO, the initial retention force of the Novaloc® is similar to the Ball System but lower than the Locator R-Tx®. The difference between the two CAS could be related to the mechanical properties of the RD material (polyethylene for Locator R-Tx® vs PEEK for Novaloc®) and to their design. The Locator R-Tx® offer a more extensive range of initial retention, followed by the Novaloc® and the Ball System with a similar range. In this study, we found that all the three AS offer appropriate initial retention, except NR and LG, with retention values lower than 5 N, chosen as our threshold for patient satisfaction.[6,12,19] Consequently, they would have no clinical interest in terms of retention in 1-IRMO. These low-retention RDs can nevertheless be helpful in some cases to reassure the patient when the clinical situation already offers good prosthetic retention. Except for two Novaloc® RD (NK and NB) where no difference in initial retention was observed in our protocol, each CAS RD provides specific initial retention, offering a choice between 4 levels for the Locator R-Tx® and 5 for the Novaloc®. The

practitioner is thus allowed to choose according to the clinical situation and the patient's needs. The Ball System offers a similar range of initial retention as the Novaloc®, but its variable adjustment may decrease the specificity of the chosen position, as evidenced by the little difference observed between B_{med} and B_{max} groups.

Therefore, CAS should be preferred to choose between different levels of initial retention, particularly Locator R-Tx® for high initial retention requirements.

The purpose of our study was to compare the initial retention of different AS on a 1-IRMO aligned with the insertion axis. However, the clinical situation often differs from this idealized model. Two or more implants are generally preferred for IRMO, creating interimplant angulations affecting initial retention, particularly for CAS.[8,10,16,18,25] Practitioners need to localize their implant according to the clinical situation but limit their interimplant angulation, especially in the sagittal plane, to reach the initial retention found in this study.[11] Moreover, patients require stable retention over time to be satisfied. The measurement of initial retention only is a severe limitation of this in vitro study and it would be interesting to compare the evolution of retention for these different AS. Indeed, in vitro studies have already shown that the high initial retention of the classic Locator® was necessary to compensate for a rapid decrease over time due to RD wear, unlike the more stable BAS.[5] Wear of the RD can also be due to insertion/removal procedures in its housing. The use of tools designed for the AS and their meticulous use is recommended to avoid any deformation or premature wear that could affect retention. In binocular photographs, we observed some scratches due to the activation of the lamellae even if we used the dedicated tool (Suppl Fig. 1). Finally, prosthesis cleaning solutions can sometimes affect retention properties.[29-31] All these clinical parameters could be investigated in further studies.

According to our results, CAS should be preferred: (i) in situations of low vertical prosthetic space, although they have a larger cross-section compared to the 2.25 mm standard diameter for BAS, and (ii) when initial retention is required to be higher, (e.g., in lingual parafunction, bruxism, or poor surface of sustentation). The standard 2.25 mm diameter BAS should be preferred: (i) in situations with low bone width and (ii) if the required retention is not strong (e.g., disabled patient).

The impact of implant numbers and angulation on RD retention, the multiplicity of available AS, and the evolution of their retention over time are other interesting clinical parameters to consider in future perspectives. These recommendations should be seen in the context of other essential aspects such as: (i) the implementation time, and the mastering of the system by the practitioner and the prosthetist, (ii) the easy placement and removal of the prosthesis by the patient, (iii) the inevitable frequent adjustments and repairs, and (iv) the patient compliance for recall.

CONCLUSION

This study, therefore, proposes a standardized material and method allowing intra- and inter-AS comparison simulating a 1-IRMO aligned with the insertion axis. Within the highlighted limitations, initial retention was significantly higher for the Locator R-Tx® than for the Ball System and the Novaloc®. Except Novaloc® Red and Locator R-Tx® Gray, the tested AS provide satisfactory retention on the first day of oral use with a retention force greater than 5 N.

Further studies are needed to analyze the impact of the number of AS retaining the prosthesis, their angulation to the insertion axis, and their behavior over time which will condition their future maintenance needs.

FIGURE AND TABLE LEGENDS

Table 1: Initial retention force of the different RD of the Ball System, the Locator R-Tx®, and the Novaloc® (*, Qualitative data only; SD, standard deviation).

Fig. 1: Experimental set-up. (a) Lower resin block with implant and abutment, (b) Mounting flange, (c) Upper resin block with two-piece matrix, (d) Load cell.

Fig. 2: Control of the models. Measurement of (a) the RD main slit width from binocular images for BAS and (b), the angulation between the insertion axis and matrix housing from CT-scan acquisitions for CAS.

Fig. 3: Width of the RD main slit for BAS: Kruskall-Wallis test shows a significant statistical difference between B_{low} and B_{max} only (****, $p < 0.0001$; ns, non-significant difference).

Fig. 4: Comparison of the initial retention of the different retention devices inside of each attachment system. The difference is significant between all the Locator® RD; between all the Novaloc® RD (except between NK and NB); between B_{low} and B_{max} positions of the Ball System. (**, $p < 0.01$; ***, $p < 0.001$; ****, $p < 0.0001$; ns, non-significant difference).

Fig. 5: Comparison of the initial retention of the different attachment systems inside of each retention group (****, $p < 0.0001$; ns, non-significant difference). Inside the maximum, medium, and low retention groups, there is a significant difference respectively between LW and the other AS (NK, NB, B_{max}), between LP and the other AS (NG, NY, B_{med}), between LB and the other AS (LG, NR, NW, B_{low}). No statistical differences were found between the others; ns: non-significant.

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Chapitre 3 : Evaluation de la perte de rétention et de l'usure

Introduction

L'analyse de la littérature effectuée dans la première partie de ce travail de thèse et l'étude *in vitro* réalisée dans la seconde partie montrent que les nouveaux SAC tels que le Locator R-Tx® et le Novaloc®, associés à la PACM retenue sur 1 ou 2 implants, offrent une gamme de rétention initiale plus large ou des niveaux rétentifs mieux compartimentés comparés aux SAB comme le Ball System ou aux anciens SAC comme le Locator® classique ou l'ERA®. Mais se pose la question de savoir si ces nouveaux SA sont capables de maintenir leur rétention dans le temps et s'ils présentent une meilleure résistance à l'usure.

D'un point de vue clinique, la perte de retention est la diminution de la force de rétention initiale au cours du temps liée à l'usure du SA. Cette usure se manifeste par une perte de substance due au frottement ou à la déformation des surfaces entre les parties mâles et femelles. Notre analyse de la littérature montre qu'elle est principalement liée à des actions mécaniques : forces occlusales notamment au cours de la mastication, manœuvres d'insertion-désinsertion visant à nettoyer la prothèse hors de la bouche, ou mise en place du DR dans son boitier à l'aide d'outils adaptés. En effet, les facteurs thermiques (température buccale) et chimiques (salive, bains de bouche, produits de désinfection des prothèses) y ont peu d'influence. Quel que soit le SA considéré, l'usure concerne principalement les parties femelles, en particulier le DR conçu dans un matériau moins rigide pour s'user préférentiellement (polyéthylène pour le Locator R-Tx®, PEEK pour le Novaloc®, alliage métallique pour le Ball System), son remplacement étant plus facile et moins coûteux, laissant le pilier implantaire en alliage de titane intact ou avec une usure très discrète sous forme d'abrasion et de rayures localisées.

Les objectifs de cette partie sont :

1) Appliquer le protocole expérimental mis en place à partir de l'analyse de la littérature (chapitre 1), et utilisé dans la détermination de la rétention initiale (chapitre 2) pour évaluer la perte de rétention (en %) et l'usure de 3 DR de chaque SA (Ball System, Locator R-Tx® et Novaloc®) après 10 000 cycles d'insertion-désinsertion (CID) équivalents cliniquement à une durée d'environ 5 ans.

2) Réaliser une analyse comparative de la perte de rétention :

    a. Comparaison intra-système (comparaison des DR d'un même SA) : 3 des 4 DR en polyéthylène du Locator R-Tx®, 3 des 6 DR en PEEK du Novaloc® et 3 positions du DR métallique du Ball System ;

    b. Comparaison inter-système (comparaison des 3 SA entre eux) au sein de groupes de rétention similaire ;

    c. Comparaison des données obtenues avec celles disponibles dans la littérature.

3) Réaliser une analyse comparative et qualitative des schémas d'usure des DR (localisation, sévérité)

Matériels et Méthodes

La perte de rétention est évaluée comme la différence relative (%) entre la force de rétention initiale (moyenne sur les 10 premiers CID) et la force de rétention après un certain nombre de cycles (100, 1000, 5000, 10 000 CID). Cette perte de rétention est positive lorsque la force après chargement cyclique est inférieure à la force initiale, une perte de rétention négative correspond à un gain de rétention. Les signes caractéristiques de l'usure sont : rugosité de surface (abrasion, rayure, éraflure, rainure), perte de substance, fissure, fracture, déformation avec changement évident de dimension. Pour chaque SA, trois DR ont été sélectionnés, un dans chaque catégorie de rétention (faible, moyenne, maximale). Le matériel utilisé est identique à celui décrit au chapitre précédent : implants (n=4), piliers implantaires (n=4), DR (n=8). La perte de rétention est évaluée sur une machine de fatigue et sur une machine universelle de traction après différents CID (100, 1 000, 5 000, 10 000). L'usure qualitative des parties mâles et femelles est évaluée sur une loupe binoculaire pour le Ball System et au micro-CT pour le Locator R-Tx® et le Novaloc®. Le nombre d'échantillons inclus dans l'étude permet de détecter une différence de l'ordre de 5N avec une puissance statistique de 0.8 et un niveau de significativité de 0.05.

Résultats et Discussion

Nous avons fait le choix de simuler une perte de rétention et une usure après 10 000 CID. La plupart des études utilisent un nombre de cycles variables entre 5 000 et 50 000 CID [18-23]. Si l'on considère les SAB et le Locator® classique, il semble que 10 000 CID soit suffisant pour atteindre la perte de rétention maximale [16,18,23-25]. Le Locator R-Tx® présente la plus grande variation de rétention au cours du temps, sa perte de rétention (en %) est précoce, ce SA perd plus de la moitié de sa rétention initiale en fin de test : en particulier LW (60,2 ±5,9N à 15,0 ±8,1N ; 75,9 ±11,0%), suivi de LP (36,9 ±8.9N à 15,4 ±10,6N ; 58,1 ±26,7%), et de LB (22,2 ±7,5N à 9,4 ±3,8N ; 54,0 ±20,4%). Le Novaloc® est le système dont la rétention est la plus stable, voire augmente au cours du temps : NK (18,9 ±1,4N à 20,8 ±2,2N ; -11,1 ±16,5%) ; NG (13,7 ±1,1N à 12,9 ±1,9N ; 4,5 ±20,4%) ; NW (6,5 ±7,7N à 7,7 ±2,5N ; -17,6 ±42,0%). Le Ball System présente une rétention plutôt stable au cours des cycles sauf pour le DR le plus faible : B_{max} (19,9 ±4,6N à 14,3 ±2,9N ; 24,5 ±25,9%) ; B_{med} (13,8 ±2,8N à 10,8 ±3,1N ; 21,9 ±16,6%), B_{low} (7,7 ±3,4N à 3,1 ±1,1N ; 49,7 ±28,6%).

Pour chaque groupe de rétention (faible, moyenne ou élevée), le Locator R-Tx® présentant la rétention initiale la plus importante, souffre de la plus grande perte de rétention. Après 10 000 cycles, son niveau de rétention est comparable aux autres SA, excepté pour le groupe de faible rétention où LB conserve une rétention finale supérieure à $B_{low.}$

Avant l'expérimentation, les piliers et le DR du Ball System présentent des signes épars d'usure liés aux outils d'assemblage ; le test de fatigue provoque également l'apparition de rayures et de rainures à l'équateur de la boule et au sommet des lamelles. Les piliers du Locator R-Tx® et du Novaloc® sont indemnes d'usure. Seul le Novaloc® montre une absence d'usure à la fois sur les parties mâles et femelles. Le Locator R-Tx® présente une altération significative des cercles concentriques en contre-dépouille à l'intérieur de son DR.

Conclusion

A partir du dispositif expérimental mis en place dans le chapitre précédent pour évaluer la rétention initiale de 3 SA sur une conception de PACM retenue sur 1 implant, nous avons effectué une comparaison intra- et inter-système de la perte de rétention et de l'usure de ces SA. La perte de

rétention est significativement plus élevée pour le Locator R-Tx® que pour le Ball System et le Novaloc® et semble corrélée à l'usure observée essentiellement sur les DR de chaque SA. Le Novaloc® est le système le plus stable. Malgré la perte de rétention, les valeurs de rétention obtenues semblent suffisantes et dans la limite de rétention acceptée par le patient pour une PACM retenue sur 1 implant après 10 000 CID, sauf pour le DR le plus faible du Ball System.

Perspectives

La perte de rétention et l'usure conditionnent les besoins de maintenance en clinique. Une usure significative ayant été identifiée sur les DR des différents SA, il serait intéressant de compléter cette étude par une caractérisation quantitative de l'usure (variation de diamètre interne, ouverture des lamelles) qui pourra être corrélée à la perte de rétention.

De même, l'utilisation d'au moins deux implants étant la norme en clinique, il sera également intéressant d'étudier l'influence de l'angulation implantaire, du nombre d'implants, de l'angulation inter-implantaire, de l'angulation du DR par rapport à l'axe d'insertion sur l'évolution de la force de rétention au cours du temps.

Article 3

Les travaux de cette partie sont détaillés dans la version préliminaire de l'article ci-dessous en vue d'une soumission dans *Journal of the Mechanical Behavior of Biomedical Materials*.

Retention loss and qualitative wear of three attachment systems for implant retained-mandibular overdentures: An in vitro study.

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ABSTRACT

Background. The stud-shaped attachment systems (AS) with different shape designs (ball, cylindrical, conical) and materials (metallic, plastic, or a combination of both) are commonly used to provide better retention and stability in implant-retained mandibular overdentures (IRMO).

Purpose. The purpose of the present study was to evaluate and compare the retention loss and the wear (patterns, location) of three resilient unsplinted AS: a well-established ball attachment system (BAS) and two more recent cylindrical attachment systems (Locator R-Tx® and Novaloc®).

Materials and methods. The implants, their corresponding abutments, the color-coded or position-coded retention devices (RD), the matrix metal housing were incorporated within CAD/CAM resin blocks and cyclically loaded with 19.6 N along the implant axis in a chewing machine to simulate 10,000 insertion-removal cycles (IRC). At cycle 10; 100; 1,000; 5,000; and 10,000; the retention force was measured using a universal testing machine. The wear patterns were examined using a micro-computed tomography X-ray for CAS or a binocular magnifier for BAS.

Results. The three AS showed different retentive behavior along time. The Locator R-Tx® lost retention-early and abruptly and all its RD lost more than 50 % of their retention after 10,000 IRC. The retention of the Ball System slightly varies over time, the final retention loss in B_{med} and B_{max} groups being lower than 25 % of the initial retention. Only Novaloc® remains stable with even a slight tendency to increase (18.87 ±1.42 N to 20.80 ±2.18 N). Wear is located at the top of BAS gold RD, the equator area of the ball abutment in BAS, and inside the plastic RD of CAS especially Locator R-Tx®. Implant abutment of the CAS shows no significant wear.

Conclusion. After 10,000 IRC, corresponding to approximately 5-years clinical use, almost all RD provide retention force over 5 N, which could be sufficient to maintain satisfaction in most of the patients. The retention loss observed most prominently for the Locator R-Tx®, then for the Ball System, seems to correlate with the wear observed on their RD. The Novaloc® provides the most stable retention overtime and shows no signs of wear.

Keywords. Initial retention force, ball and cylindrical attachment systems, implant-retained mandibular overdenture.

INTRODUCTION

The removable complete denture or overdenture is a medical device that replaces missing natural teeth in edentulous patients. These prosthetics can be readily inserted and removed from the mouth by the patient for cleaning. It is possible to enhance their retention thanks to attachment systems (AS) present on residual roots or dental implants. The implant-retained mandibular overdenture (IRMO) stabilized on 1[1,2] but mainly 2 implants[3,4] inserted in the interforaminal area (Fig. 1) provides numerous benefits at the functional, structural, and psychosocial levels when compared to the conventional mandibular overdentures.[5] The unsplinted socket or stud-shaped AS, with different prosthodontic shape designs (ball, cylindrical, conical) and materials (metallic, plastic, or a combination of both)[2,6,7] are clinically the most common used in restorative dentistry due to a low initial cost and processing compared to treatments with implant-fixed rehabilitation (e.g., an easy to handle and process, a lower technique sensitivity, a modest space requirement, self-alignment, an easy oral hygiene management, and future modifications or repairs simple to perform).[5,8]

The most clinically used and investigated is the ball attachment system (BAS),[2] as Ball System (Nobel Biocare AB, Göteborg, Sweden) similar to Dalbo® Plus (Cendres et Métaux SA, Biel-Bienne, Switzerland) (Fig. 2). The cylindrical attachment systems (CAS) have been promoted by the manufacturers to improve the initial retention, reduce wear and the retention loss. The most popular is the Locator® Legacy (Zest Dental Solutions, Escondido, California, USA) introduced in 2001 to overcome the limitations of the first CAS and the limitations of BAS such as large vertical space requirements and limited applicability for angulated implants.[8] Recent CAS try to enhance their performance, especially to overcome greater angular discrepancies, by introducing new designs for the implant abutment and the retentive device (RD), wear-resistant coatings of the abutment, and high-performance polymers (e.g. polyetheretherketone (PEEK)) for RD manufacturing. Locator R-Tx® (Zest Anchors, Escondido, CA, USA) (Fig. 2) which replace Locator® Legacy, are equipped with polyethylene RD and abutment titanium nitride coating surface, and Novaloc® (Valoc AG, Möhlin, Switzerland, distributed by Straumann AG, Basel, Switzerland) (Fig. 2)

provide PEEK RD and abutment amorphous diamond-like carbon coating surface. A limited number of studies have examined these new CAS.[5,8,10]

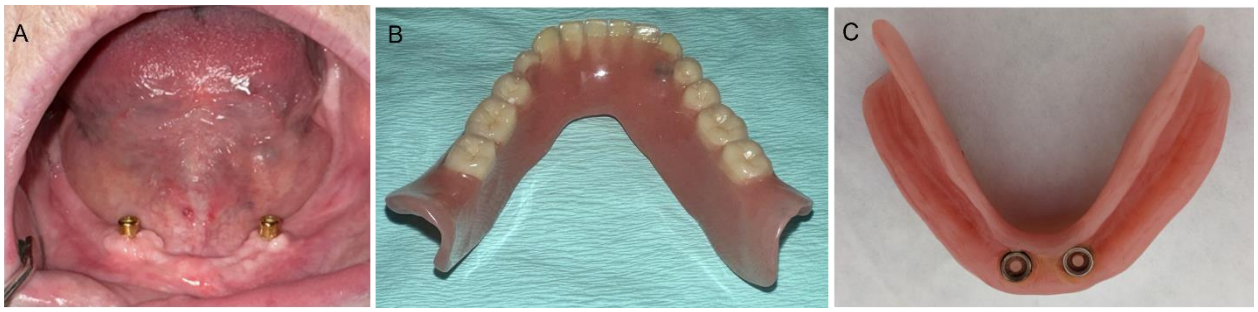

Figure 1: Complete edentulous mandible treated by two-implant-retained mandibular overdenture. (A) Complete edentulous mandible with two implant abutments in symphysis area. (B), two-implant-retained mandibular overdenture. (C), Intaglio of the conventional removable complete mandibular overdenture with the two-piece matrix.

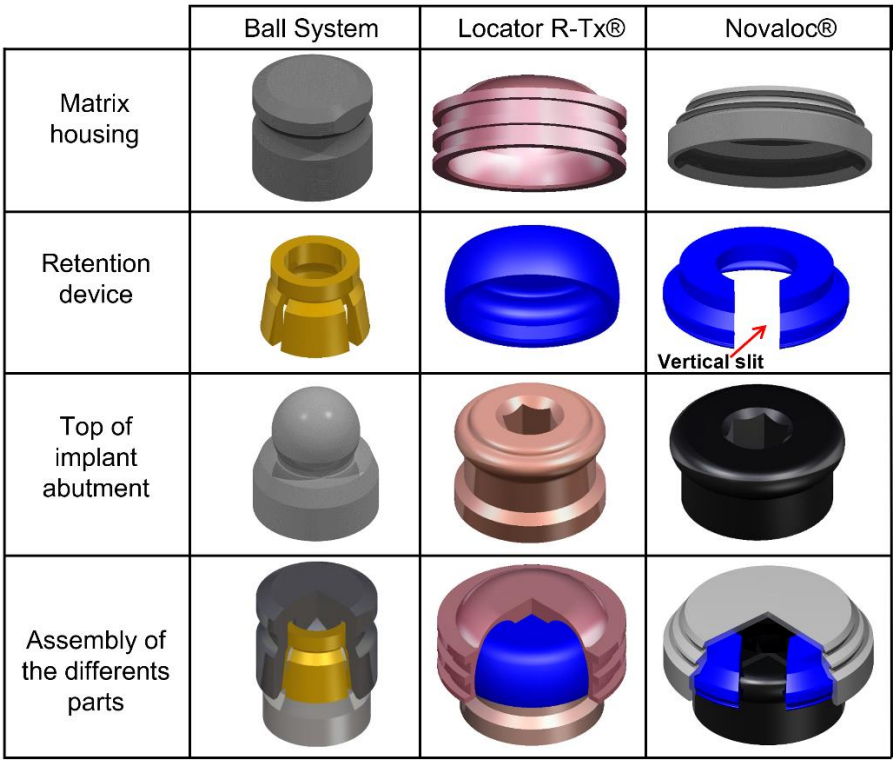

Figure 2: Schematic diagram of the attachment systems included in the study: Ball System, Locator R-Tx® and Novaloc).

The choice of anchorage system is crucial, as it has a direct impact on the patient ability to manage their prosthesis, the amount of aftercare and cost required, overall patient satisfaction, and clinical success but to our knowledge there is no evidence for a preferable indication of any type of unsplinted AS.[5] The success of an IRMO depends mainly on the AS initial retention force and its evolution over time (e.g., wear, retention loss, need of maintenance).[11]

AS retention decreases over time based on deformation and surface alterations of the RD occurring during insertion and removal of the IRMO (e.g., for the denture cleaning outside the mouth) as well as during functional (e.g. chewing) and parafunctional movements.[8] Wear is defined as the loss of material due to the contact between the RD and the implant abutment during these movements. Clinical studies shows that retention loss and wear occur over time in all conventional BAS and CAS.[1,12-18] To simulate the clinical use of the AS in in vitro studies, investigators performed insertion-removal cycles (IRC) sometimes associated with chewing cycles, or chewing cycles (CC) only.[11] For the BAS, it appears that the combination of titanium alloy ball with precious alloy or plastic RD remains the most suitable configuration over time to limit wear and retention loss, the wear patterns being located at the retention area (the equator of the ball abutment and the tip of the RD).[11] Few available studies suggest that the retention force of Locator R-Tx® Pink RD decreases significantly compared to Novaloc® Yellow RD.[5,8] These new CAS show an undamaged abutment surface while their RD revealed considerable signs of wear located mostly on the top without detectable loss of materials.[8] Locator R-Tx® displayed more identifiable signs of wear and deformation (notches on the outer edge and in the RD base) than Novaloc® (alterations with a polished-like surface in their undercuts, especially in areas close to the slot).[8]

No study has assessed the retention loss and the wear patterns of three different color-coded RD of Locator R-Tx® or Novaloc®, and position-coded RD of the Ball System. The purpose of this in vitro study was to simulate a clinical 1-IRMO to evaluate and compare the retention loss and the qualitative wear (wear patterns, location) of 3 RD of these AS after 5 years clinical use.

MATERIALS AND METHODS

Experimental models and attachment systems

All the materials investigated in this study - e.g. a clinical 1-IRMO simulating upper and lower resin blocks, the implants (n=4 for each AS), the abutments (n=4 for each AS), the matrix metal housing (n=4 for CAS and n=12 for BAS), the RD (n=8 for each AS) - were presented in a previous in vitro study on the initial retention of these AS.[19] According to this study, initial retention was defined as the average of the maximal dislodgement force to separate the male and female parts of the AS during the first 10 IRC performed on a universal testing machine (Shimadzu Autograph AGS-X). Three RD are selected for each CAS: Locator R-Tx® blue (LB), pink (LP), white (LW), and Novaloc® white (NW), green (NG), black (NK). For the Ball System, 3 groups (B_{max}, B_{med}, B_{low}) were created corresponding to 3 calibrated retention levels (maximum, medium, and low).

Fatigue test and retention force measurements

Cyclic loading of the samples was performed using a chewing simulator with four units (CS-4, SD Mechatronik, Germany) with a crosshead speed set to 60 mm/min, a displacement along the implant axis of 2 mm and an axial load of 19.6 N to ensure proper locking of the device at every cycle. Tests were conducted at a frequency of 0.12 Hz, under air, at room temperature. At cycles 90, 990, 4,990, and 9,900, samples were removed from the chewing simulator in order to measure, for each sample, the average retention force during 10 consecutive cycles on the universal testing machine.

Retention loss, which characterizes the decrease of retention over time, is evaluated in percent (%) as the relative difference in retention between the initial (after 10 IRC) and intermediate (after 100, 1,000, or 5,000 IRC) or final situation (after 10,000 IRC) according to the following equation:

$$Retention\ Loss\ at\ cycle\ C\ (\%) = \frac{Initial\ retention\ (N) - retention\ at\ cycle\ C\ (N)}{Initial\ retention\ (N)}\ x\ 100$$

Qualitative assessment of the wear

Before and after cyclic loading, 3D images of the RD, separated from its matrix housing, were acquired using a micro-computed tomography X-ray Quantum FX µCT (PerkinElmer, Inc, Waltham, Massachusetts, USA) with a pixel size of 10 µm for the CAS. After segmentation, the external surface of each RD was reconstructed using marching cube algorithm in CTan® software. The 3D images of the RD before and

after 10,000 IRC were aligned using GOM® inspect software with the local best fit of their external surfaces, not damaged by cyclic loading. Distance map projected onto the unworn RD highlights worn areas.

For the BAS, metallic artifacts prevent the use of CT-scan acquisition for wear analysis. 2D images of the two-piece matrix (RD and matrix housing) and the ball abutment were acquired at x50 magnification using a binocular magnifier Leica MC170 HD (Leica Microsystems AG, Heerbrugg, Switzerland) in order to characterize the wear at the top of the RD and at the equator of the ball abutment.

Statistical analysis and sample size calculation

Numerical variables were expressed as the mean ± standard deviation (SD). The statistical analysis was performed using Prism GraphPad version 7.04. The normality of the distribution was tested with the D'Agostino-Pearson Normality test to choose between non-parametric and parametric tests to apply. According to the result of the previous study,[19] three categories of AS were created depending on the initial retention, with the best RD for each AS for this group: low retention (B_{low}, LB, NW), medium retention (B_{med}, LP, NG), and maximum retention (B_{max}, LW, NK). Within each retention group, the measurements obtained were compared, as well as within each AS. A non-parametric Kruskall-Wallis, one-way Anova or two-way Anova test was applied, followed by a Tukey Test. One RD was considered as the statistical unit. Differences were considered significant at $p < 0.05$. The sample size (n=8 per group) was selected by the litterature[8,10,17,19,22-24,27,29,30] and to detect a variation in retention of 5.2 N with a statistical power of 0.8 and a significance level of 0.05 for BAS (standard deviation of 3.7 N)[22].

RESULTS

Retention

The retention force (N) provided by each RD for increasing numbers of insertion-removal cycles are reported in Table 1 and illustrated in Figure 3. The Locator R-Tx® shows the highest significant decrease in retention over time (Fig. 3). The LW has the most important variation (60.2 ±5.9 N to 15.0 ±8.1 N) followed by the LP (36.9 ±8.9 N to 15.4 ±10.6 N) and the LB (22.2 ±7.5 N to 9.4 ±3.8 N). Novaloc® (Fig. 3)

and Ball System (Fig. 3) have rather stable retention in each RD during the different cycles except for B_{low} (7.7 ±3. 4 N to 3.1 ±1.1 N) which shows a statistically significant decrease from 5,000 IRC.

After 10,000 IRC, Figure 2 shows no significant difference between LW, LP and LB in final retention whereas every RD of the Novaloc® and the Ball System still provide distinct levels of retention (Fig. 4).

Retention device	Manufacturer's retention	Retention force (N)					Retention loss (%)			
		10	100	1000	5000	10000	10-100	10-1000	10-5000	10-10000
B_{low}	5 -10 N	7.66 ±3.43	5.17 ±3.02	4.55 ±2.60	3.79 ±1.91	3.09 ±1.08	26.42 ±32.00	32.03 ±34.50	47.38±20.42	49.75 ±28.61
B_{med}	10 -15 N	13.78 ±2.83	12.63 ±3.76	11.33 ±4.53	12.48 ±4.64	10.84 ±3.08	7.49 ±23.22	17.27 ±28.31	9.63 ±26.58	21.94 ±16.63
B_{max}	15 -22 N	19.88 ±4.61	14.83 ±6.66	21.63 ±5.73	16.52 ±6.49	14.27 ±2.92	26.42 ±32.00	-15.48* ±47.67	12.05 ±41.40	24.54 ±25.90
LB	Low**	22.18 ±7.50	19.37 ±3.30	18.24 ±5.84	12.73 ±4.92	9.42 ±3.84	7.92 ±19.79	10.49 ±38.81	41.39 ±21.20	53.96 ±20.43
LP	Medium**	35.97 ±8.87	24.61 ±4.35	26.71 ±8.32	25.08 ±15.02	15.43 ±10.59	29.28 ±15.34	23.26 ±27.18	30.39 ±43.78	58.07 ±26.66
LW	High**	60.20 ±5.95	44.39 ±3.94	33.28 ±3.93	20.45 ±9.20	15.03 ±8.10	25.85 ±8.05	43.93 ±10.65	66.88 ±12.48	75.87 ±11.01
NW	7.35 N	6.47 ±7.74	6.65 ±1.92	6.53 ±2.16	6.43 ±1.27	7.74 ±2.50	-4.08* ±34.15	-1.12* ±32.73	0.62 ±16.13	-17.56* ±42.05
NG	16.18 N	13.71 ±1.13	12.02 ±1.97	13.26 ±3.26	12.13 ±2.44	12.93 ±1.93	11.50 ±19.11	2.03 ±29.36	10.54 ±23.03	4.46 ±20.40
NK	25.01 N	18.87 ±1.42	17.98 ±1 .96	17.09 ±1.12	19.70 ±1.83	20.80 ±2.18	3.78 ±4.57	9.03 ±8.46	-4.79* ±10.86	-11.06* ±16.48

Table 1: Mean retention and retention loss of the retention devices after different insertion-removal cycles (negative values correspond to an increased retention, ** Only Qualitative data available).*

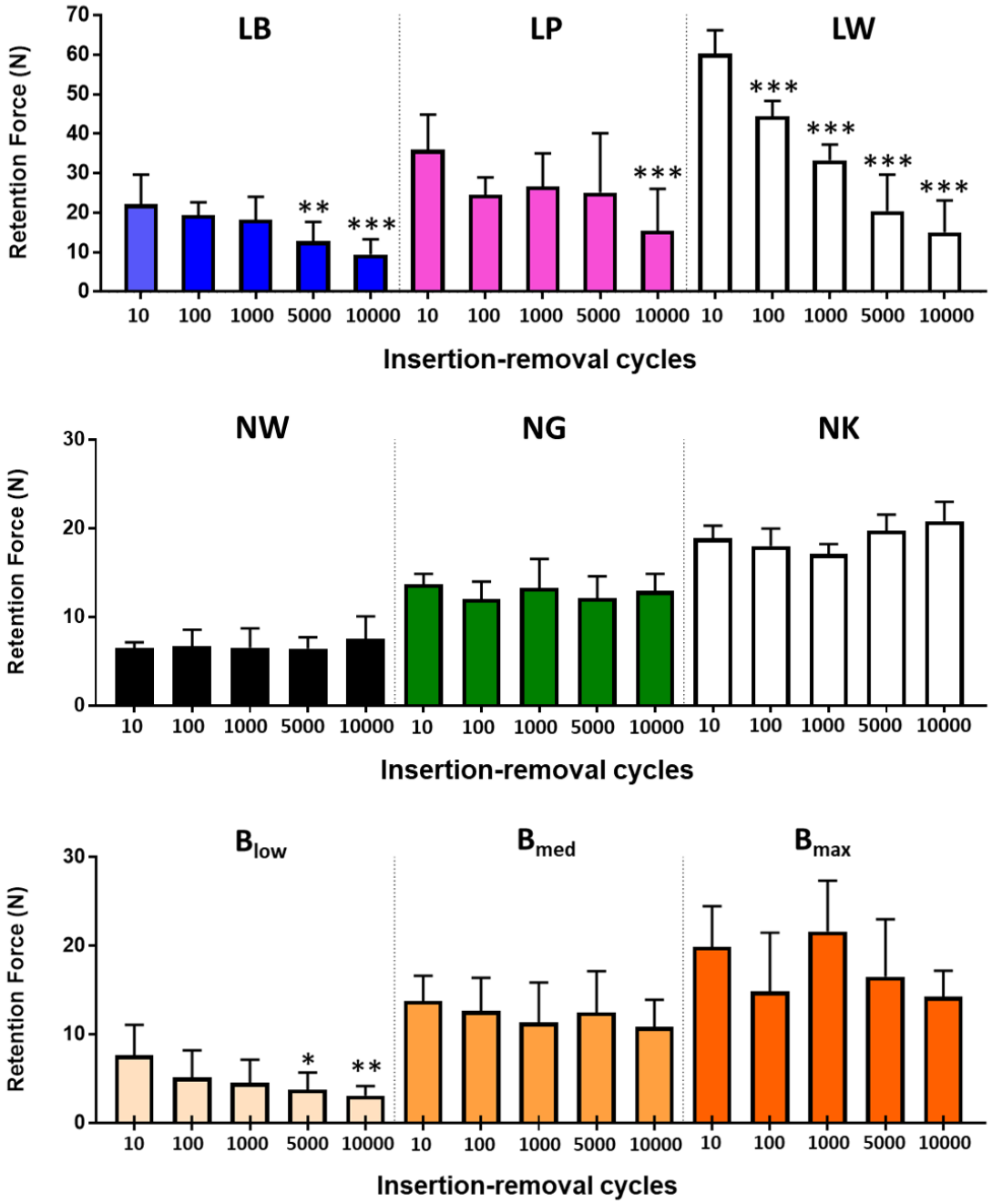

Figure 3: Evolution of the retention force of the different devices for increasing numbers of insertion-removal cycles between each attachment system. Locator R-Tx® (LB, LP, LW). Novaloc® (NW, NG, NK). Ball System (B_{low}, B_{med}, B_{max}). The difference is significant compared to the initial retention force of the considered RD (, $p < 0.05$, **, $p < 0.01$).*

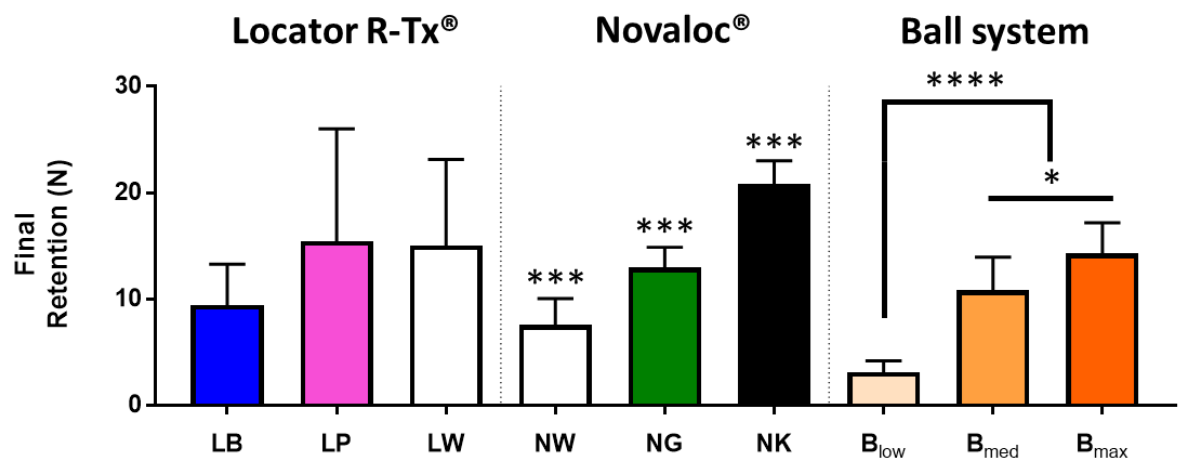

Figure 4: Comparison of the retention force after 10,000 insertion-removal cycles of the different retentive devices between each attachment system.

Interestingly, the Locator R-Tx® statistically higher in the 3 groups of initial retention, drastically decrease in final retention to show no statistical difference except with B_{low} in the low retention group (Fig. 5). Due to its stable retention over time (Fig. 4), Novaloc® shows final retention values comparable to the Locator R-Tx® and is therefore significantly different from the Ball system in the maximum and low groups (Fig. 5).

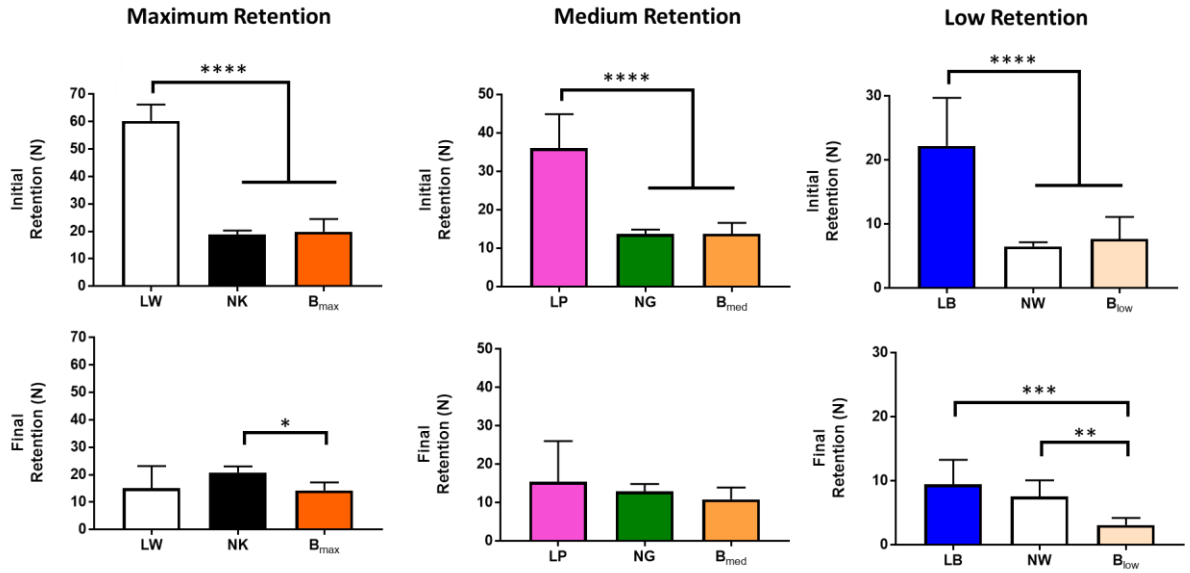

*Figure 5: Comparison of the retention of the different devices between each retention group. (A) Initial retention (after 10 insertion-removal cycles) (B) Final retention (after 10,000 cycles). Statistical difference: *, p < 0.05; **, p <0.01; ***, p < 0.001; ****, p < 0.0001.*

Retention loss

Data on the evolution of retention loss (%) for each RD are presented in Table 1 and illustrated in Figure 6. The retention loss of the Locator R-Tx® occurs early, abruptly, and significantly from 100 cycles. At 1000 cycles, LB has lost 10% of its initial retention, LP more than 20%, and LW more than 40%. After 10,000 cycles, each RD lost more than half of its initial retention: LW (75.9 ±11.0%), LP (58.1 ±26.7%), and LB (54.0 ±20.4%) (Fig. 6). The three RD of the Ball System behave differently: the retention loss of B_{low} increases gradually until 49.8 ±28.6% whereas B_{med} and B_{max} show some significant variations (Fig 6). B_{med} retention loss oscillates between 7.5 ±23.2% and 21.9 ±16.6%. After a first decrease in retention at 100 IRC, B_{max} shows an increase in retention (-15.5 ±47.7%) at 1,000 IRC before a progressive decrease until 10,000 IRC (24.5 ±25.9%). The retention loss of Novaloc® is insignificant over time, this system appears much more stable than the two others and gains even slightly in retention for NW (-17.6 ±42.1%) and NK (-11.1 ±16.5%). Consequently, in each retention group, after 10,000 IRC, the highest retention loss is observed for the Locator R-Tx®, followed by the Ball System and finally the Novaloc® with its negligible retention loss (Fig. 7).

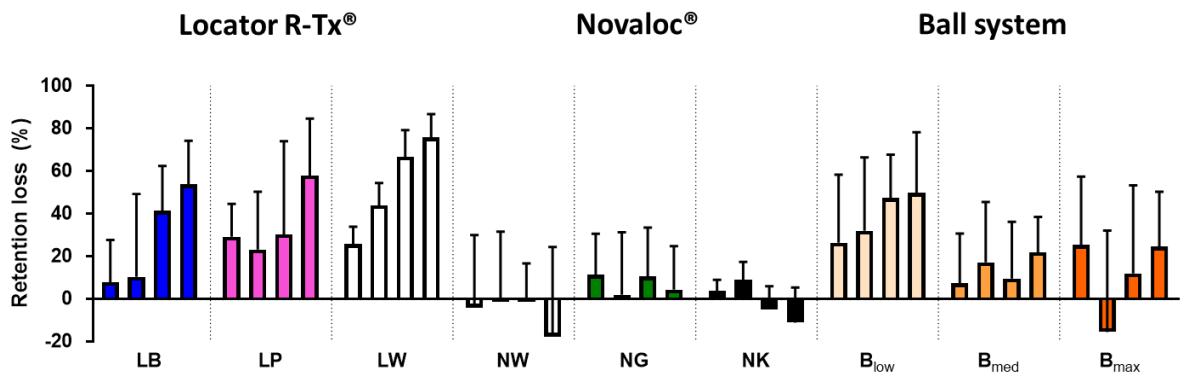

Figure 6: Evolution of the retention loss of the different devices during different insertion-removal cycles between each attachment system at 100; 1,000; 5,000 and 10,000 cycles. (A) Locator R-Tx®, (B) Novaloc®, (C) Ball System.

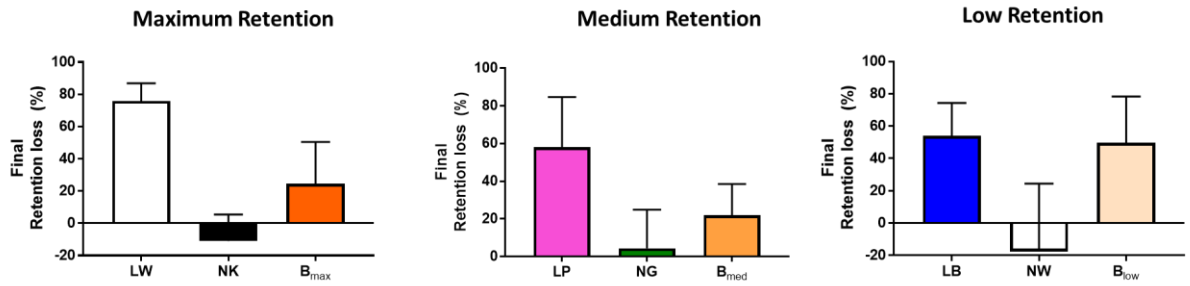

Figure 7: Comparison of the retention loss of the different devices between each retention group.

Wear

The figure 8 shows the wear patterns of the different male parts. Before the experiment, the implant abutment of the Ball System (Fig. 8A) shows signs of wear related to the assembly tool (the torque wrench to fix the male part in the resin block) (Fig. 8B). After cyclic loading, significant scratches and grooves are observed only at the equator area of the ball abutment (Fig. 8C). Only minor scratches of the coating are observed on the implant abutment of Locator R-Tx® and Novaloc®, after tightening and cyclic loading (Fig. 8D-E).

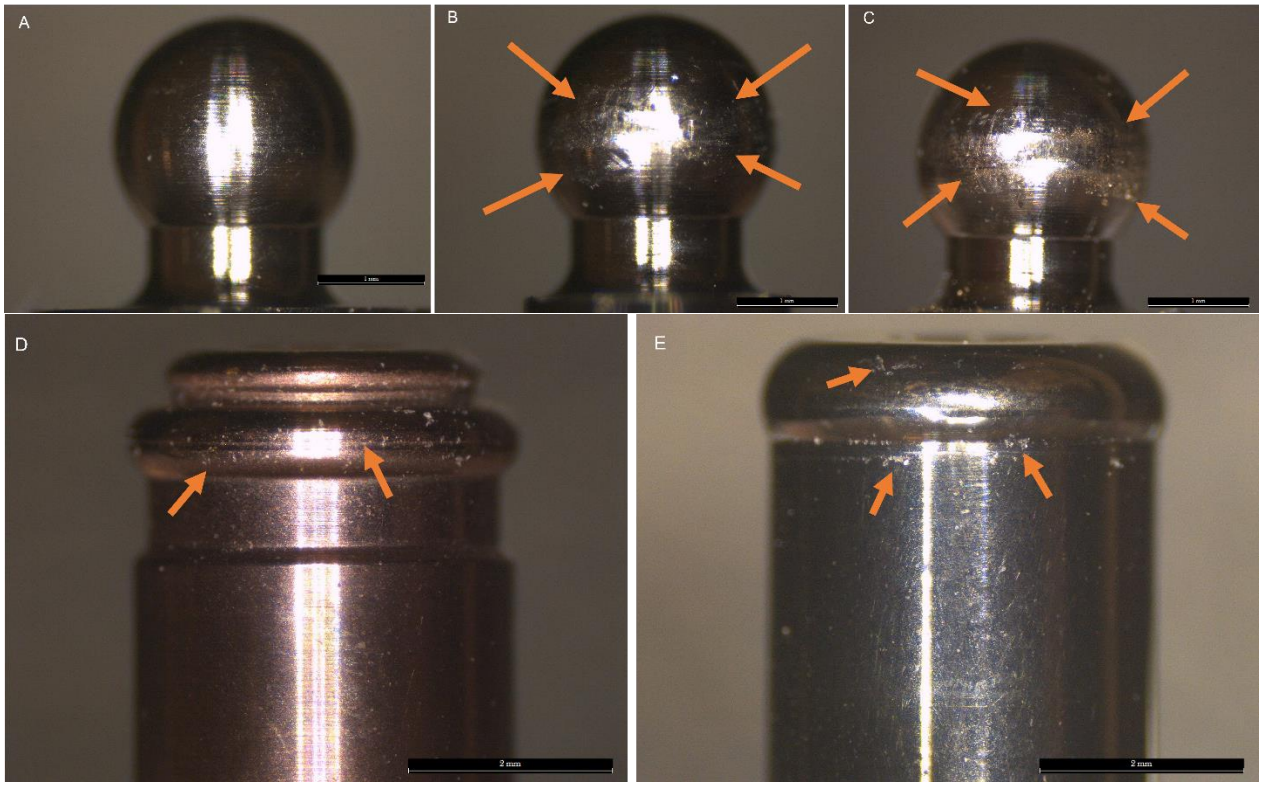

Figure 8: Wear patterns of a sample of abutment of the different attachment systems. Ball System abutment opposite to B_{low} retention device, (A) Before tightening, (B) After tightening, (C) After 10,000 insertion-removal cycles (first line). Significant wear located in the ball equator area (see arrows). Locator R-Tx® abutment opposite to LW retention device (second line, D) and Novaloc® abutment opposite to NK retention device (second line, E) after 10,000 insertion-removal cycles. No relevant sign of wear observed on the abutment except some scratches of surface coating (see arrows).

Slight signs of wear are detected on the Ball System RD after using the specific screwdriver to calibrate the RD (Fig. 9B). After cyclic loading, significant scratches and grooves are observed at the top of gold lamellae with blunt edges and sometimes material loss (Fig. 9C).

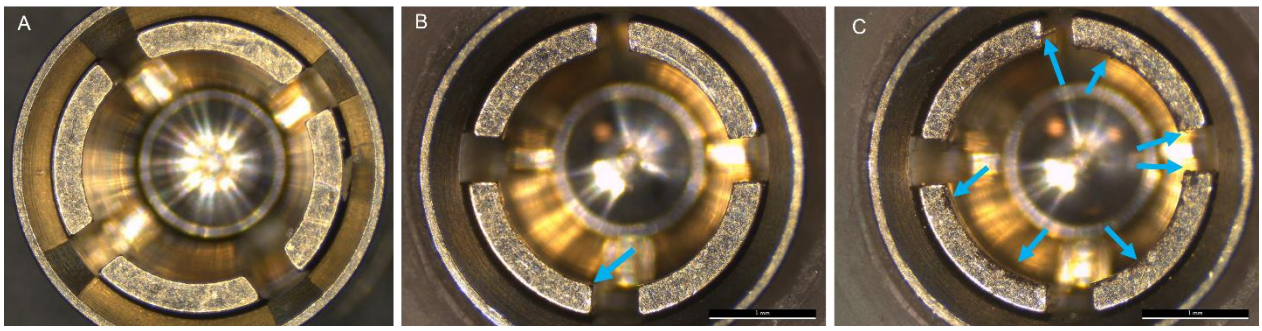

Figure 9: Wear patterns of a retention device sample of the Ball System. Before tightening. (B) After tightening. (C) After 10,000 insertion-removal cycles. Wear located at the top of lamellae (see arrows).

For the RD of Locator R-Tx® and Novaloc®, no relevant sign of wear is observed due to the assembly tool before the test. Cyclic loading generates significant wear on Locator R-Tx® RD (Fig. 10A-C): scratches and groves on the inner surface and material loss especially along the two concentric retentive circles. The distance map shows an increase of the smallest diameter on the inner edges (Fig. 10C). In the Novaloc® system, only minor damage is observed (Fig.10D-F).

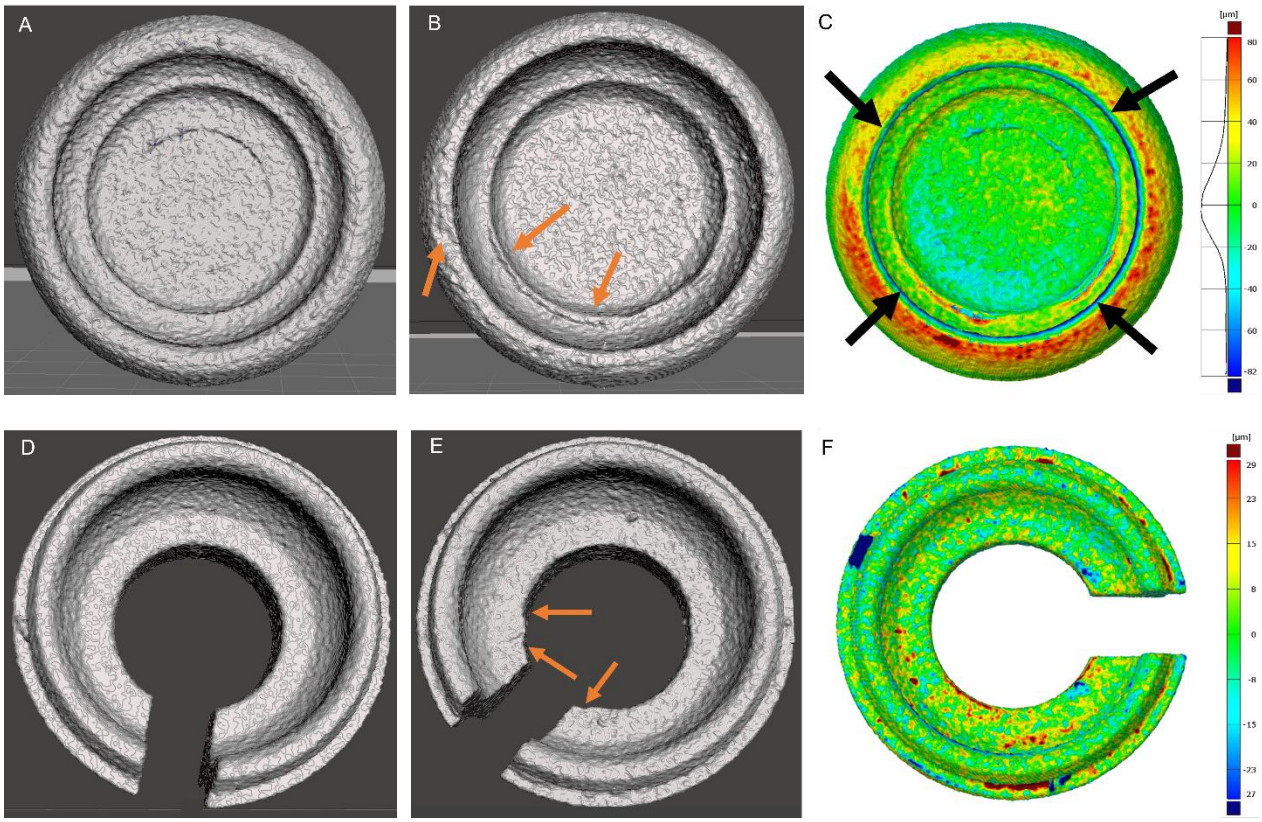

Figure 10: Wear patterns of a sample of the Locator R-Tx® White (first line) and Novaloc® Black (second line) retention devices. (A) and (D) Before the test. (B) and (E) After fatigue test, deformation or material loss indicated by arrows. (C) and (F) distance maps of the two devices, the blue circle indicated by arrows illustrates the material loss on the internal edges of Locator R-Tx® RD.

DISCUSSION

In in vitro studies, the retention loss is measured as the difference between initial retention (after 1 or 10 IRC) and final retention after a certain number of cycles along or around the implant axis. There is no consensus on the choice of performed cycles (e.g., IRC and/or CC, loading direction, intensity, cross-head speed), on the final number of cycles, and on the partial or complete separation of the AS at each cycle. Similarly, to assess the wear of AS, investigators simulated a clinical use between 1 and 10 years by using IRC and /or CC.[11] Approximately 1,000 to 1,800 IRC based on 3,[1,20] 4,[6,14,21] or 5[22] denture removals a day or 400,000 CC[23] or a combination of both[24] correspond to a 1-year clinical use. One study used 14,600 IRC to simulate clinical retention loss of BAS,[6] while others considered 10,000 IRC[5] or 30,000 IRC sufficient for CAS.[8,25] Regardless the BAS and the Locator® Legacy, it seems that the maximal retention loss is reached at about 10,000 IRC.[7,22,26-28]. According to these

findings, we decided in this study to perform 10,000 IRC with complete separation between male and female parts along a vertical axis, corresponding to a simulated fatigue period of 5.5 years based on 5 insertions and removals of the IRMO a day.

As a result of the correlation between patient satisfaction and expected retention force, some authors suggested that a retention of 5-7N is sufficient for IRMO[23,29-31] (without precision on the implant number), others investigators advised 10-20N for 2-IRMO.[21,26,32,33] According to these observations, the final retention force of all the tested AS is acceptable to reach patient satisfaction, except B_{low} (3.09 ±1.08 N) and NW (7.74 ±2.50 N).

For medium and maximum levels of retention, our study shows slight variations of the Ball System retention over time. These results are in accordance with other studies[7,26,34] that showed an increase in retention during the first 500 to 1,500 cycles followed by a progressive decrease, the overall retention loss being moderate. The retention increase can be explained by the cyclic hardening of the gold alloy during the first cycles whereas the progressive decrease is related to the wear observed at the top of the retentive device and at the equator of the ball abutment. Similarly, two studies noticed signs of abrasion and minor flattening in the equator area of the male part after cyclic loading (50,000 IRC on 1-IRMO for Wolf et al.[7] and one-year clinical use of 2-IRMO for Jabbour et al.[17]). Jabbour et al.[17] also noticed scratches and spots of metal deposits on the RD.

Locator R-Tx® with its abutment made from titanium carbon nitrid with Dura-Tec™ coating resulting in a 32% increase in hardness and 26% more wear resistance[35] is considered an improvement of Locator® Legacy whose retention was shown to decrease over time from 21% to 95% for 1-IRMO[7,22] or 2-IRMO.[10,23,28,29] With an overall retention loss observed between 54.0 ±20.4% and 75.9 ±11.0% for Locator R-Tx®, our results on 1-IRMO show no noticeable difference between these two AS. For the most retentive RD (LW), retention loss progresses regularly and is significant as soon as 100 IRC. For LP and LB, retention is stable over longer periods (10-1,000 IRC for LB, 100-5,000 IRC for LP) and retention loss is found significant only after 5,000 IRC for LB and 10,000 IRC for LP.

The few studies assessing the performances of Locator R-Tx® concerned only the pink RD in 2-IRMO and thus cannot be directly compared with our results.[5,8,35] Before a progressive decrease in retention, three studies first noticed an increase up to 100 IRC,[5] 500 IRC[8] or 2,000 IRC[35] that can be connected with the relative increase observed between 100 and 1,000 IRC in our study. Similar to our results,

retention loss was observed in all studies but became significant only after 20,000 IRC.[8] This retention loss is directly attributable to the wear of the polyethylene RD, planned to be regularly replaced, and in particular the smoothing of the inner edges responsible for locking the Locator R-Tx®, also observed by Wichmann et al.[8] Additionally, polyethylene RD is soft and can perform pivoting movements in the matrix housing inducing a looser locking of the AS and a higher variability of the measured retention.

On the contrary, Novaloc® maintains a stable retention over time with no significant loss up to 10,000 IRC. Despite differences in methodology, this result has been confirmed by the literature for 2-IRMO.[5,8,10,35] This stability can be related to the absence of wear on the abutment and the minor damage close to the slot of the RD, comparable to the observations of Wichmann et al.[8] The association of the amorphous diamond-like carbon wear-resistant coating for the abutment with a RD manufactured in PEEK, a polymer with high mechanical properties, seems to be the better configuration to limit damage on the AS and ensure a constant retention force over time. The higher stiffness of PEEK material also limits the variability of the retention measurements with a tight locking of the AS.

Wear and retention loss should be taken into consideration for clinical use. 10,000 IRC correspond to approximately 5-years clinical use. As claimed by some authors, the final retention force of the SA should not fall below 5-7 N to maintain patient satisfaction. Therefore, all RD, except B_{low}, remain functional after 10,000 IRC with our protocol. Nevertheless, different daily use of these AS inevitably leads to differences in their rate of wear. We can thus extrapolate our conclusions and warn patients that the Locator R-Tx® and Ball system will require significantly more frequent maintenance than the Novaloc®.

The present in vitro study performed in 1-IRMO has some limitations. Therefore, the retention force measured cannot be directly transposed to a clinical situation where 2-IRMO is generally recommended. Nevertheless, this experimental setup allows a controlled comparison of the AS without introducing patient-related factors and implant factors (implant number, angulation between implant). To simplify the exerted forces on implants, only a unidirectional vertical force was applied, while in a clinical situation, a rotational movement will inevitably be present. So, no eccentric loading was applied on the upper resin block, wear characterized in this study only concerns an axial loading aligned with the implant axis. The combination of vertical and rotational movement creates the

multidirectional forces, which will undoubtedly exacerbate the wear of the AS.[5] This study is conducted in dry conditions. Various wet mediums have been used in previous studies to imitate as close as possible the clinical environment (saline solution, demineralized water, artificial saliva) but no consensus on an ideal medium has yet been found.[11] In clinically wet conditions, moisture absorption can create dimensional changes and sometimes modify the flexibility of the material. Polyethylene shows higher water absorption levels than PEEK.[5] Clinically, when dentures are stored dry, a drying out of the RD will probably occur and modify the retention, potentially modifying their behavior for an unknown amount of time.[5]

CONCLUSION

This study proposes a standardized material and method allowing intra- and inter-AS comparison simulating a 1-IRMO aligned with the insertion axis. Within the highlighted limitations, the retention loss was significantly higher for the Locator R-Tx® followed by the Ball System and the Novaloc®. Only Novaloc® appear stable and show constant retention over time. After 10000 IRC, the final retention force of the tested AS ranges of the limits of patient acceptance overdenture retention force, except for B_{low} and NW. The retention loss seems correlated with wear patterns observed at the top of gold lamellae RD of BAS and inside the RD of Locator R-Tx®. This should be taken into consideration for clinical use (replacement or activation of the RD). Further studies are needed to analyze the impact of the number of AS retaining the prosthesis, their angulation to the insertion axis, and their behavior over time which will condition their future maintenance needs.

FIGURE AND TABLE LEGENDS

Figure 1: Complete edentulous mandible treated by two-implant-retained mandibular overdenture. (A) Complete edentulous mandible with two implant abutments in symphysis area. (B), two-implant-retained mandibular overdenture. (C), Underface of the conventional removable complete mandibular overdenture with area of the two-piece matrix.

Figure 2 : Schematic diagram of a standard ball attachment system (Dalbo®-Plus) and cylindrical attachment systems (Locator R-Tx®) and Novaloc®).

Figure 3: Evolution of the retention force of the different devices for increasing numbers of insertion-removal cycles between each attachment system. Locator R-Tx® (LB, LP, LW). Novaloc® (NW, NG, NK). Ball System (B_{low}, B_{med}, B_{max}). The difference is significant compared to the initial retention force of the considered RD (, $p < 0.05$, **, $p < 0.01$).*

Figure 4: Comparison of the retention force after 10,000 insertion-removal cycles of the different retentive devices between each attachment system.

*Figure 5: Comparison of the retention of the different devices between each retention group. (A) Initial retention (after 10 insertion-removal cycles) (B) Final retention (after 10,000 cycles). Statistical difference: *, p < 0.05; **, p <0.01; ***, p < 0.001; ****, p < 0.0001.*

Figure 6: Evolution of the retention loss of the different devices during different insertion-removal cycles between each attachment system. (A) Locator R-Tx®, (B) Novaloc®, (C) Ball System.

Figure 7: Comparison of the retention loss of the different devices between each retention group.

Figure 8: Wear patterns of a sample of abutment of the different attachment systems. Ball System abutment opposite to B_{low} retention device, (A) Before tightening, (B) After tightening, (C) After 10,000 insertion-removal cycles (first line). Significant wear located in the ball equator area (see arrows). Locator R-Tx® abutment opposite to LW retention device (second line, D) and Novaloc® abutment opposite to NK retention device (second line, E) after 10,000 insertion-removal cycles. No relevant sign of wear observed on the abutment except some scratches of surface coating (see arrows).

Figure 9: Wear patterns of a retention device sample of the Ball System. Before tightening. (B) After tightening. (C) After 10,000 insertion-removal cycles. Wear located at the top of lamellae (see arrows).

Figure 10: Wear patterns of a sample of the Locator R-Tx® White (first line) and Novaloc® Black (second line) retention devices. (A) and (D) Before the test. (B) and (E) After fatigue test, deformation or material loss indicated by arrows. (C) and (F) Matching of the two images, the blue circle indicated by arrows illustrate the material loss on the internal edges of Locator R-Tx® RD.

Table 1: Mean retention and retention loss of the retention devices after different insertion-removal cycles (negative values correspond to an increased retention, ** Only Qualitative data available).*

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Chapitre 4 : Données complémentaires

4-1. Précisions sur le matériel et méthodes de la mesure de rétention

4-1-1. Calibration du disposition de rétention du Ball System

Le Ball System ne possède qu'un seul DR, mais ce dernier est activable grâce au tournevis spécifique fourni par le fabricant. Il suffit de visser le DR au sein du boîtier métallique, dans le sens des aiguilles d'une montre, jusqu'à l'intensité de rétention souhaitée. D'après le fabricant, le couple DR/ boîtier, livré déjà assemblé est pré-activé avec une force d'environ 200g (≈ 2N) correspondant à un quart de tour. Par la suite, toute rotation d'un quart de tour, avec le tournevis d'activation fourni, augmente la rétention d'environ 200g. Le niveau d'activation le plus élevé est obtenu après 1,5 tour au maximum, soit 6 quarts de tour possible (comprenant le quart de tour initial), correspondant à une force maximale de 2 200g (≈ 22N) (Figure 1).

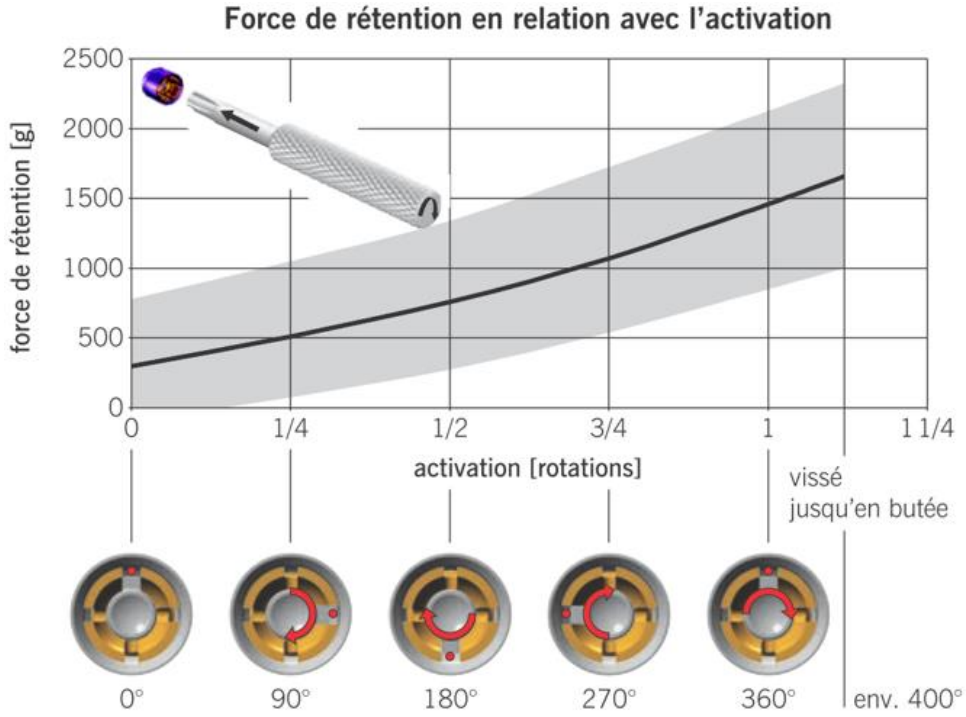

Figure 1 : Activation des lamelles rétentives du système Dalbo-Plus® à partir de la position initiale pré-activée d'un quart de tour (0°) jusqu'à la position de blocage (1,5 tour) où le système atteint sa force de rétention maximale, d'environ 2 200g (≈ 22N). Document Cendres & Métaux, Dalbo® Abutment. De L'original au système, Septembre 2017
https://www.cmsa.ch/index.php?eID=dumpFile&t=f&f=12873&token=dc5fc5b3068fe897dca53640a2fbdbd9bf874d77

Au cours de l'activation, le DR en alliage précieux est progressivement vissé au sein du boîtier métallique, de la position de base pré-activée (Figure 2A) jusqu'à la position de blocage (1,5 tour) (Figure 2B). Ceci se traduit par un enfoncement progressif du DR dans le boîtier jusqu'au plancher au cours du vissage.

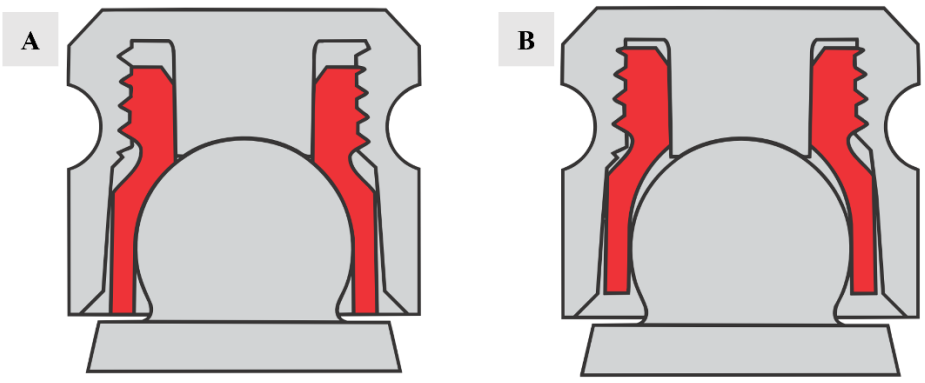

Figure 2 : Rapport entre le dispositif de rétention et le boîtier au cours de l'activation. (A) Réglage de base du couple lamelle en rouge) / boîtier (en gris) à la livraison, l'extrémité inférieure des lamelles affleure le bord du boîtier. (B) Activation maximale du couple lamelle/ boîtier par rotation du dispositif de rétention à l'intérieur du boîtier jusqu'au blocage, l'extrémité supérieure se rapproche du fond du boîtier et le système atteint sa force de rétention maximale, d'environ 1200g (≈ 12N). Document Cendres & Métaux, Mode d'emploi du système Dalbo®, Octobre 2020
https://www.cmsa.ch/index.php?eID=dumpFile&t=f&f=14957&token=5e1284d713803a31ac0c199a3e47b447f8d520b0

Pour faciliter la comparaison avec le Locator R-Tx® et le Novaloc®, nous avons décidé de calibrer 3 positions différentes du DR correspondant à 3 niveaux d'intensité de rétention : faible, moyenne, maximale (Figure 3). Pour cela, le DR a d'abord été activé jusqu'à la position de blocage (position B_{max}) pour connaitre la valeur de rétention maximale du système. Puis il a été désactivé d'un demi-tour (position B_{med}) ; et enfin il a été désactivé d'un tour (position B_{low}). Il en résulte donc trois niveaux de rétention (B_{low}, B_{med} et B_{max}), correspondant respectivement à trois intensités de rétention (faible, moyenne, élevée).

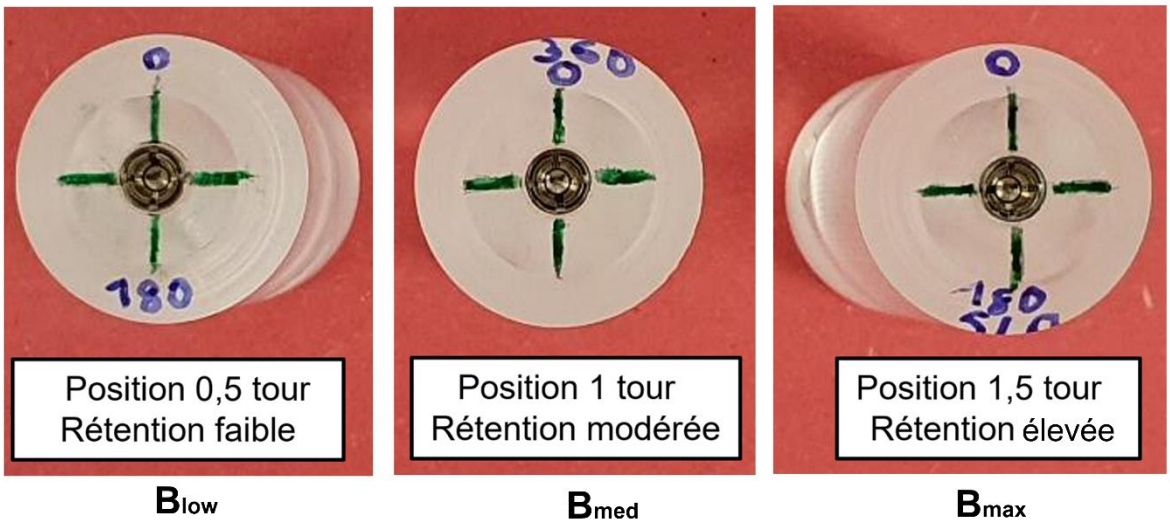

Figure 3 : Réglage du dispositif de rétention du Ball System pour obtenir trois niveaux de rétention B_{low}, B_{med} et B_{max}.

La fiabilité de la calibration a été contrôlée sur des images acquises à la loupe binoculaire Leica MC170 HD (Leica Microystems AG, Heerbrugg, Switzerland) en mesurant l'épaisseur de la fente du DR, seul paramètre variable avec la calibration, grâce au logiciel ImageJ® (plus le DR est vissé au sein du boîtier, plus l'épaisseur de fente diminue) (Figure 4), la corrélation entre l'épaisseur de la fente verticale et le niveau de rétention de chaque groupe (B_{low}, B_{med} ou B_{max}) a été vérifiée comme illustrée dans l'article du chapitre 2 (Figure 5).

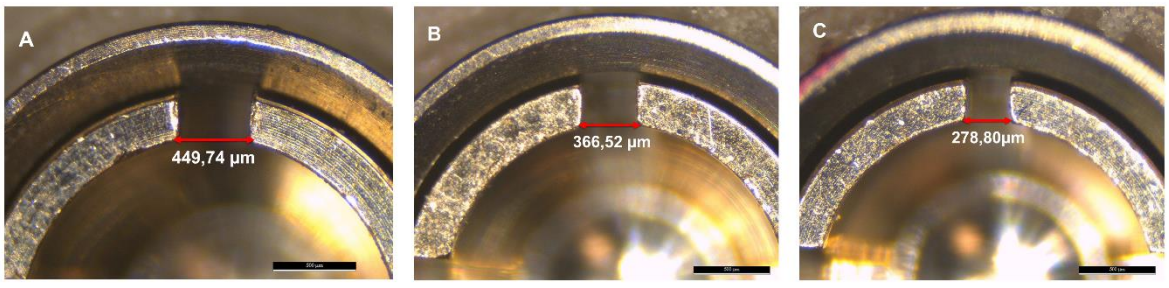

Figure 4 : Contrôle de la calibration du dispositif de rétention du Ball System après acquisition d'images à la loupe binoculaire et mesure de l'épaisseur de fente grâce au logiciel ImageJ®. Les images A, B et C représentent respectivement les niveaux d'activation B_{low}, B_{med} et B_{max}.

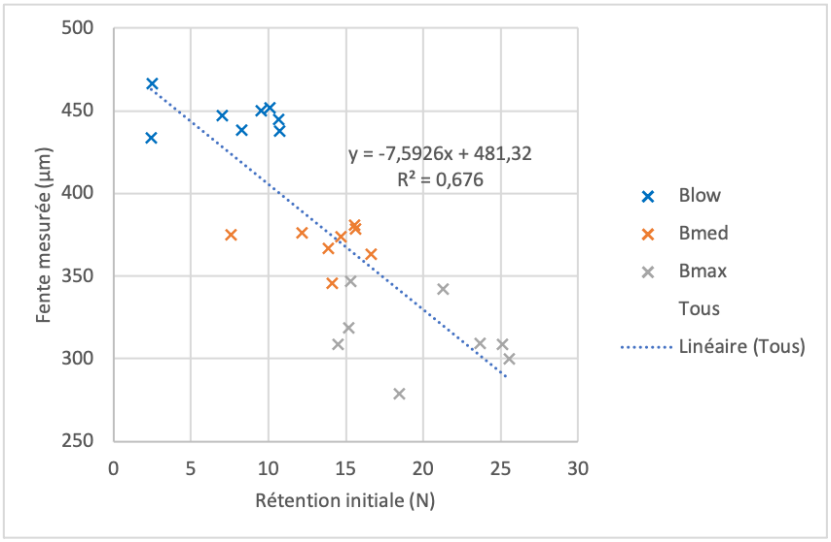

Figure 5 : Corrélation entre largeur de la fente principale et rétention initiale du dispositif de rétention du Ball System.

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4-1-2. Conception et fabrication des blocs de simulation pour chaque système d'attachement

Pour simuler une PACM retenue sur 1 implant, des blocs transparents pré-forés en résine PMMA (polymethyl methacrylate) ont été conçus et fabriqués par CFAO (conception et fabrication assistée par ordinateur) et assemblés avec les pièces implantaires et prothétiques. Les formes et dimensions des blocs tiennent compte des caractéristiques de la machine de traction (Shimadzu Autograph AGS-X) (Figures 6, 7, et 8).

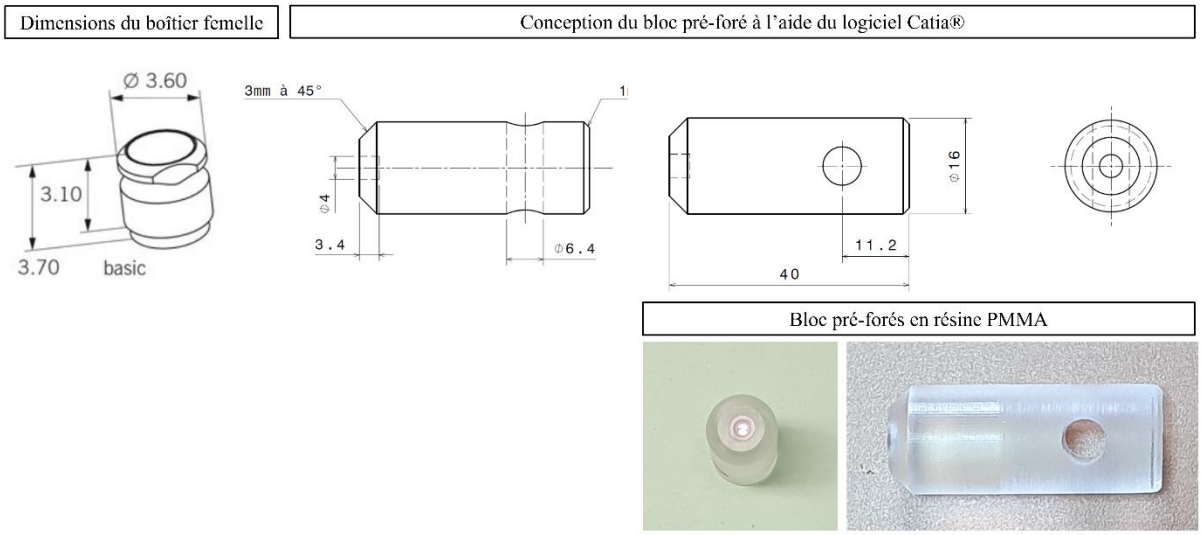


Figure 6 : Conception et fabrication du bloc pré-foré supérieur du Ball System en tenant compte des dimensions du boîtier femelle. Le logement du boîtier femelle est surdimensionné de 0,4mm. Image Cendres & Métaux (dimension du boîtier femelle).

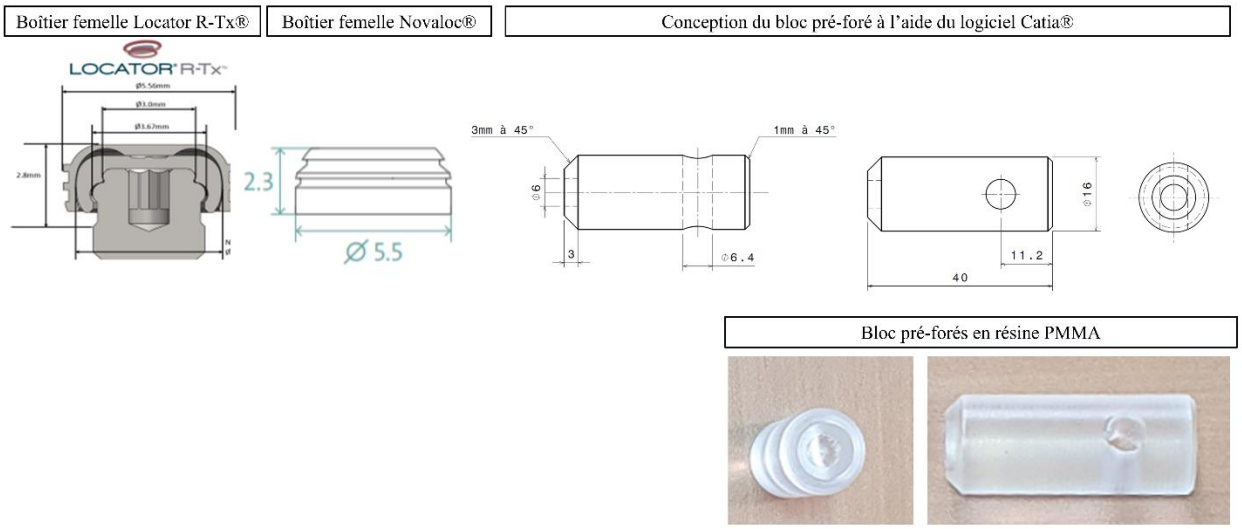


Figure 7 : Conception et fabrication du bloc pré-foré supérieur du Locator R-Tx® et du Novaloc® en tenant compte des dimensions du boîtier femelle. Le logement du boîtier femelle est surdimensionné de 0,5mm. Images Zest Anchors (dimensions du boîtier femelle Locator R-Tx®) et Straumann (dimensions du boîtier femelle Novaloc®)

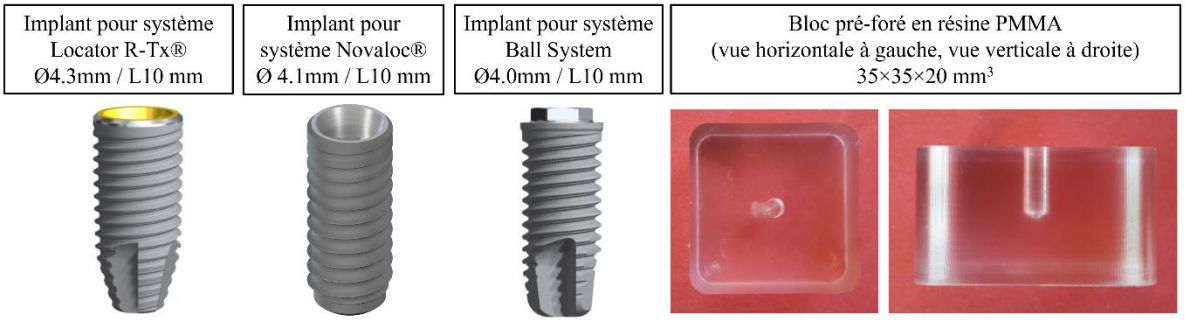


Figure 8 : Conception et fabrication du bloc pré-foré inférieur en tenant compte du diamètre et de la longueur de chaque implant : Brånemark System® Mk III Groovy Regular Platform (Ball System, Image Nobel Biocare), Nobel Parallel™ Conical Connection Regular Platform (Locator R-Tx®, Image Nobel Biocare), bone level Regular Connect, SLA® surface, Loxim® (Novaloc®, Image Straumann). Le logement implantaire est sous-dimensionné de 0,5mm.

4-1-3. Assemblage des pièces implantaires et prothétiques dans les blocs de simulation pour chaque système d'attachement

Les pièces implantaires (implants et piliers) ont été assemblées sur le bloc inférieur, simulant l'os mandibulaire, selon les recommandations de chaque fabricant. Les pièces prothétiques (boîtiers et DR) ont été assemblées sur le bloc supérieur simulant la PACM à l'aide d'une résine autopolymérisable (Tableau 2). Le bon assemblage entre le bloc supérieur et le boîtier selon le

même axe vertical a été contrôlé sur des images acquises au micro-CT, après calcul de l'angle entre le plan du boîtier et l'axe du cylindre (pour la simulation d'une PACM retenue sur 1 seul implant, le SAB est peu affecté par l'angulation) (Tableau 3).

Blocs en résine	Elément simulé	Forme	Assemblage avec les pièces prothétiques
Bloc supérieur	PAC mandibulaire	Cylindrique 40mm, Ø 16mm (préforage du logement du boîtier surdimensionné de 0,4 à 0,5mm)	Assemblage du boîtier femelle dans son logement par une résine fluide autopolymérisable (Biocryl®, Scheu Dental GmbH)
Bloc inférieur	Os mandibulaire	Cubique 35 x 35 x 20 mm (préforage du logement implantaire sous-dimensionné de 0,5mm)	Assemblage de l'implant dans son logement, et du pilier dans l'implant par vissage, respectivement 35 et 15 Ncm

Tableau 2 : Caractéristiques des blocs et assemblage des pièces implantaires et prothétiques.

	Locator R-Tx®	Novaloc®
Bloc n°1	0,79°	1,25°
Bloc n°2	2,11°	0,75°
Bloc n°3	0,98°	2,38°
Bloc n°4	1,57°	1,4°
Moyenne ± Ecart-type	1,36°± 0,60°	1,44°± 0,68°

Tableau 3 : Contrôle de l'assemblage entre le bloc « Prothèse » et le boîtier des systèmes attachements cylindriques, par calcul de l'angle entre le plan du boîtier et l'axe du cylindre.

4-1-4. Fixation des blocs de simulation sur la machine de traction, choix des paramètres et réalisation du test

La machine de traction est calibrée et paramétrée (Tableau 4) puis les blocs de simulation munis des pièces prothétiques et implantaires y sont fixés. Le point zéro est ainsi défini, dès lors que les parties mâles et femelles sont parfaitement emboîtées, et en légère compression sur le plateau de la machine (environ 0,5N). La première manœuvre de désinsertion mécanisée est effectuée jusqu'à séparation complète entre les parties mâles et femelles. Puis le bloc

« prothèse » fixée à la cellule de force est abaissé manuellement jusqu'au contact du bloc « os » pour remettre l'assemblage à zéro. Ensuite un préchargement manuel d'environ 15N est appliqué (uniquement pour les DR plastiques) pour définir un nouveau point zéro. C'est à partir de ce nouveau point qu'est déclenchée une série de 9 CID automatisés.

Cellule de force	100 N
Nombre de cycles d'insertion-désinsertion	10
Pré-chargement avant la désinsertion (dispositif de rétention plastique uniquement)	15 N
Distance parcourue	1,5 mm
Temps d'attente avant désinsertion	0 s
Temps d'attente avant insertion	0 s
Vitesse d'insertion	0,5 mm/mn
Vitesse de désinsertion	60 mm/mn

Tableau 4 : Paramètres appliqués à la machine de traction.

4-1-5. Problèmes rencontrées lors du test de traction

Sur le SA Locator R-Tx®, à cause de la rotation du DR à l'intérieur du boîtier et de le jeu entre les parties mâles et femelles (environ 4mm), il est difficile de contrôler la position du DR dans le boîtier et donc la position initiale du bloc inférieur sur le bloc supérieur (Figure 9).

Figure 9 : Variation de la position du dispositif de rétention en polyéthylène par rotation dans le boîtier du système Locator R-Tx®. Dispositif de rétention Bleu (A), Gris (B) et Rose (C).

Sur le Ball System, la déformation permanente du DR métallique en alliage précieux est à craindre au cours de l'abaissement manuel de la traverse jusqu'à la position zéro. C'est

d'ailleurs la raison pour laquelle le préchargement n'est pas recommandé. Par ailleurs, même si ce SA possède un jeu entre les parties mâles et femelles, l'absence de précharge pourrait conduire à ne pas inserrer la lamelle à fond sur le pilier. Lors du retour de la traverse à zéro, il arrive de constater que la partie femelle parfaitement assemblée sur la partie mâle au départ (Figure 10A), n'est plus parfaitement emboîtée (Figure 10B).

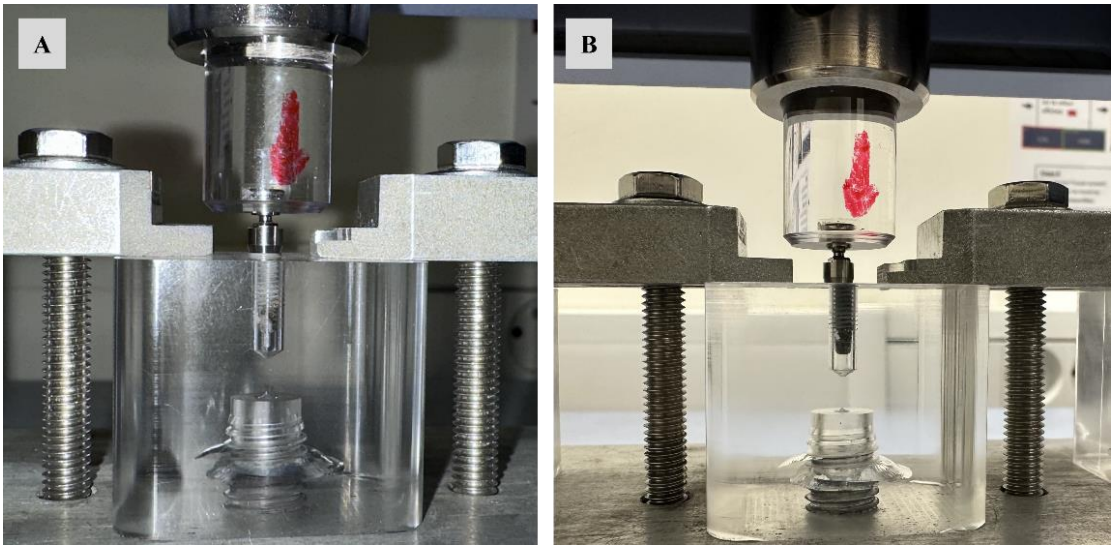


Figure 10 : Difficultés de réassemblage des parties mâle et femelle du Ball System en l'absence de précharge.

Quel que soit le SA analysé, le contrôle manuel de la vitesse d'abaissement de la traverse pour atteindre la position zéro d'origine ou la nouvelle position zéro, après la désinsertion initiale, et avant les neuf cycles automatisés, est très aléatoire.

4-2. Précisions sur le matériel et méthodes du test de fatigue

4-2-1. Fixation des blocs de simulation sur la machine de fatigue, choix des paramètres et réalisation du test

Les 8 échantillons de chaque DR ont été randomisés et divisés en deux séries (lots 1 à 4, et lots 5 à 8). Chaque série est réalisée simultanément grâce à la fixation des 4 échantillons sur la machine de fatigue à 4 unités (Figure 11). Le dispositif expérimental est ensuite paramétré (Tableau 5). Les résultats du test sont enregistrés sur l'ordinateur. La simulation est arrêtée à des stades intermédiaires (90, 990, 4990, et 9900 CID) et la force de rétention des 4 DR est à

nouveau acquise sur la machine de traction comme la moyenne de 10 CID conformément au protocole décrit dans le chapitre 2.

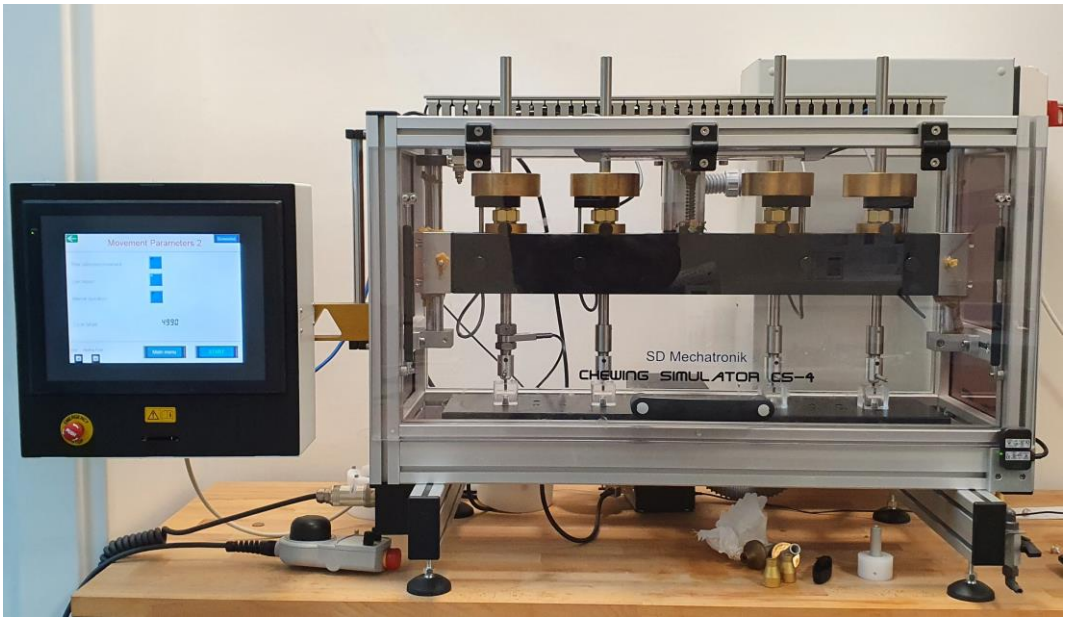


Figure 11 : Dispositif expérimental du test de simulation de la fatigue.

Cellule de force	100 N
Nombre de cycles d'insertion-désinsertion	100, 1000, 5000, 10000
Fréquence	0,12 Hz
Force exercée sur chaque unité	20 N
Type de mouvement	Linéaire uniaxial (vertical) Pas de mouvement horizontal
Distance parcourue (descente ou remontée)	2 mm
Vitesse (descente ou remontée)	1 mm/s
Temps d'attente avant désinsertion	0 s
Temps d'attente avant insertion	0 s
Vitesse de désinsertion	60 mm/mm

Tableau 5 : Paramètres appliqués à la machine de fatigue.

4-2-1. Problèmes rencontrés lors du test de fatigue

Quel que soit le SA considéré, la machine de fatigue utilisée ne possède qu'un seul capteur de force raccordé au premier couple de blocs supérieur et inférieur. Ainsi, il n'est pas possible de vérifier au cours de la simulation si une force de rétention est bien détectée au niveau des trois

autres couples de blocs et qui rassurerait sur leur bon positionnement l'un par rapport à l'autre. C'est d'ailleurs pourquoi la simulation est arrêtée à des stades intermédiaires (90, 990, 4990 et 9900 CID) de sorte à réaliser l'acquisition de la force de rétention des 4 DR sur la machine de traction. Une comparaison des résultats obtenus sur les deux dispositifs sera présentée par la suite dans le manuscrit.

4-3. Précisions sur le matériel et méthodes de l'analyse d'usure

4-3-1. Fixation des blocs de simulation sur le micro-CT

Un support (Figure 12) en forme de dôme avec 4 puits a été spécialement conçu sur ordinateur et fabriqué par impression 3D pour recevoir les 4 blocs munis des 4 échantillons cylindriques de chaque série pour l'acquisition d'images au micro-CT haute résolution.

Figure 12 : Support de fixation des blocs "Prothèses" pour l'acquisition d'images au micro-CT.

4-3-2. Précisions sur le choix entre micro-CT et loupe binoculaire

Les tests préliminaires (Figures 13 à 17) ont montré que l'acquisition d'images du Ball System au micro-CT n'était pas exploitable à cause de l'absence de contraste entre le boitier en acier inoxydable et le DR en alliage précieux, et des artéfacts générés au contact des rayons X. Dès lors, nous avons décidé de faire l'acquisition d'images au micro-CT uniquement pour les parties femelles du Locator R-Tx® et du Novaloc®, et une acquisition à la loupe binoculaire pour les lamelles métalliques du Ball System.

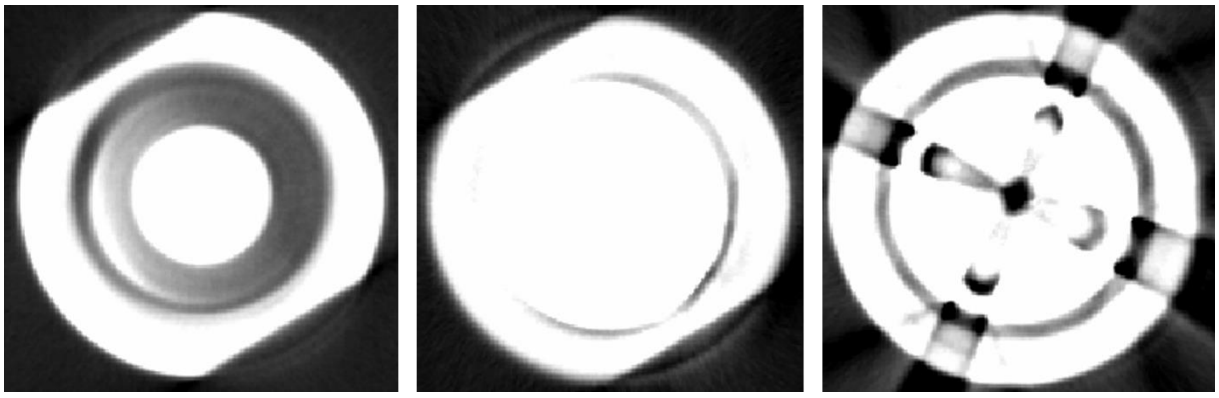


Figure 13 : Visualisation grâce au logiciel de reconstruction CTan® d'une série de trois images 2D à différents temps d'acquisition au micro-CT, du couple boîtier métallique / dispositif de rétention métallique du Ball System. L'absence de contraste ne permet pas d'isoler le dispositif de rétention du boîtier.

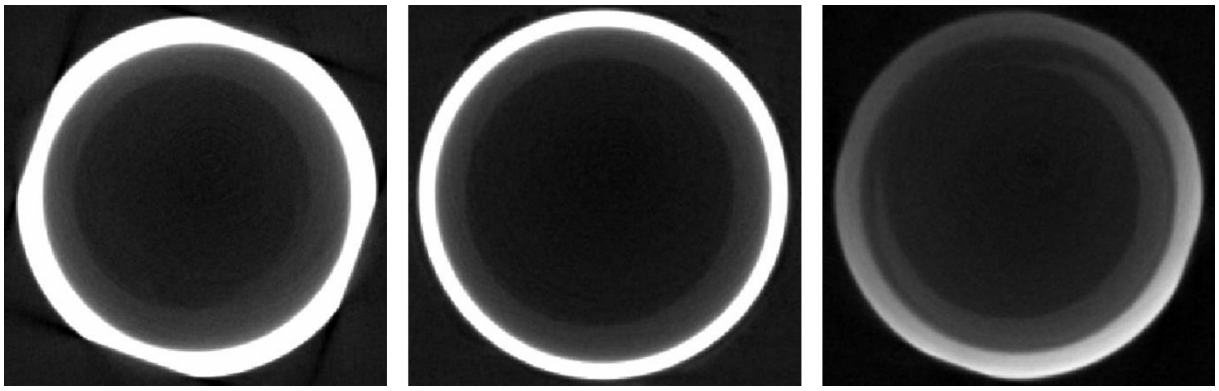


Figure 14 : Visualisation grâce au logiciel de reconstruction CTan® d'une série de trois images 2D à différents temps d'acquisition au micro-CT, du couple boîtier métallique / dispositif de rétention en nylon du Locator R-Tx®. Le contraste rend possible l'étude de l'évolution du diamètre du dispositif de rétention au sein du boîtier au cours du temps.

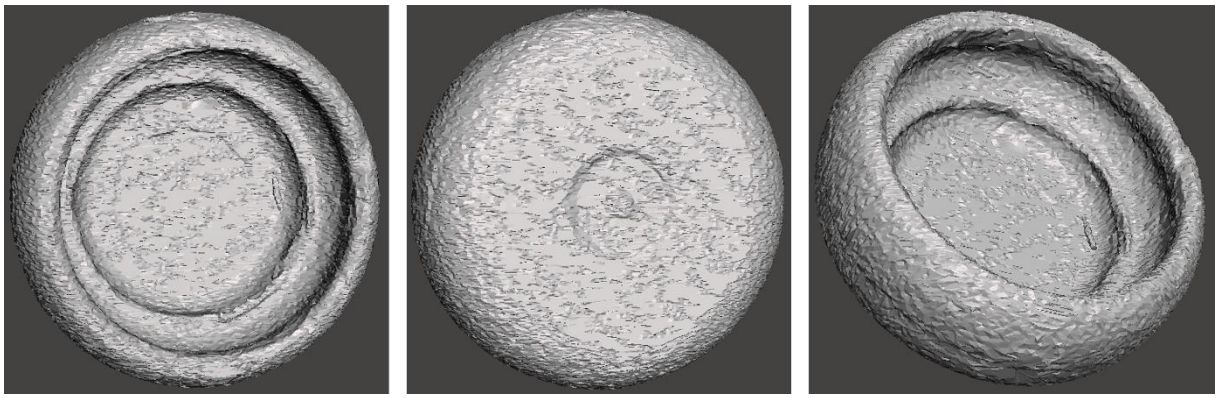


Figure 15 : Visualisation grâce au logiciel de modélisation 3D Meshmixer® d'une image (trois vues différentes) du dispositif de rétention du système Locator R-Tx®.

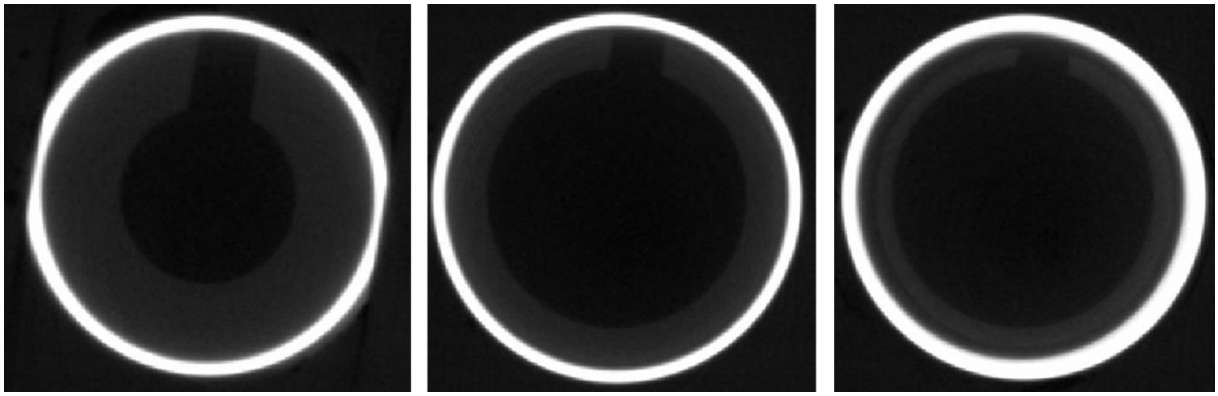


Figure 16 : Visualisation grâce au logiciel de reconstruction CTan® d'une série de trois images 2D à différents temps d'acquisition au micro-CT, du couple boîtier métallique / dispositif de rétention en plastique du Novaloc®. Le contraste rend possible l'étude de l'évolution du diamètre du dispositif de rétention au sein du boîtier au cours du temps.

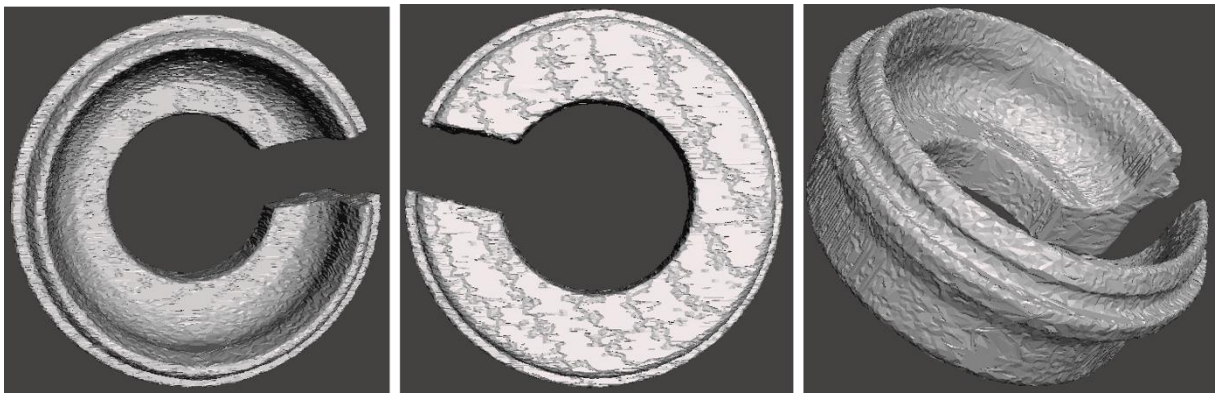


Figure 17 : Visualisation grâce au logiciel de modélisation 3D Meshmixer® d'une image (trois vues différentes) du dispositif de rétention du système Novaloc®.

4-3-2. Fixation des blocs de simulation sur la loupe binoculaire

Les images des parties mâles et femelles du Ball System sont acquises grâce à une loupe binoculaire. Le cylindre est positionné sur le plateau de la loupe de façon standardisé et le dispositif est paramétré (Tableau). L'image acquise, observée est enregistrée sur l'ordinateur connecté à la loupe (Figure 18).

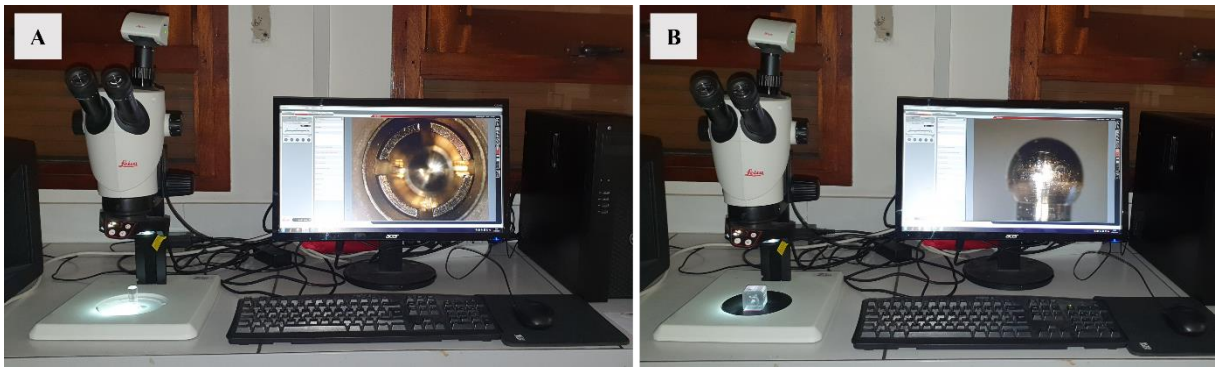
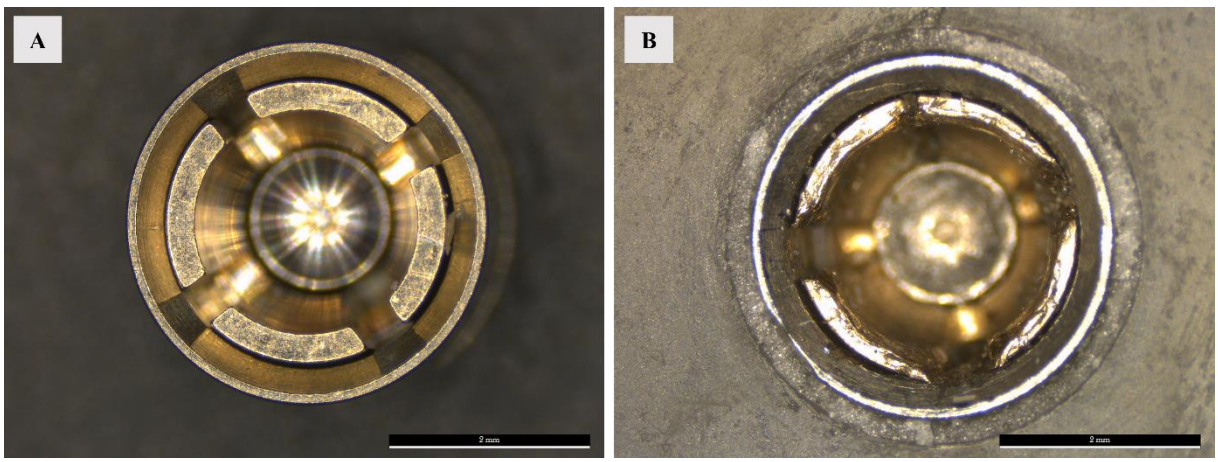


Figure 18 : Dispositif expérimentation d'acquisition d'images à la loupe binoculaire. (A) Acquisition sur le bloc « Prothèse » (boîtier, lamelle, fente). (B) Acquisition sur le bloc « Os » (pilier boule).

4-3-3. Caractérisation de l'usure sur la loupe binoculaire

L'observation à la loupe binoculaire de la partie femelle d'un SAB, neuf (Figure 19A) et usé récupéré sur une PACM après utilisation clinique (la durée clinique d'utilisation ne nous a pas été communiquée) (Figure 19B) permet de se rendre compte de son schéma d'usure et des perspectives pour évaluer quantitativement l'usure, par exemple en suivant l'évolution du diamètre au cours du temps (Tableau 6). Partant de ce constat, nous avons envisagé de caractériser l'évolution du diamètre du boîtier, ainsi que les diamètres interne et externe des lamelles (Figure 19C). Mais finalement, nous avons jugé non pertinente la mesure de ces paramètres après l'observation d'une partie femelle après 10000 CID (Figure 19D). En effet, aucun changement évident de diamètre ou déformation significative n'a été mise en évidence sur les lamelles ou le boîtier.



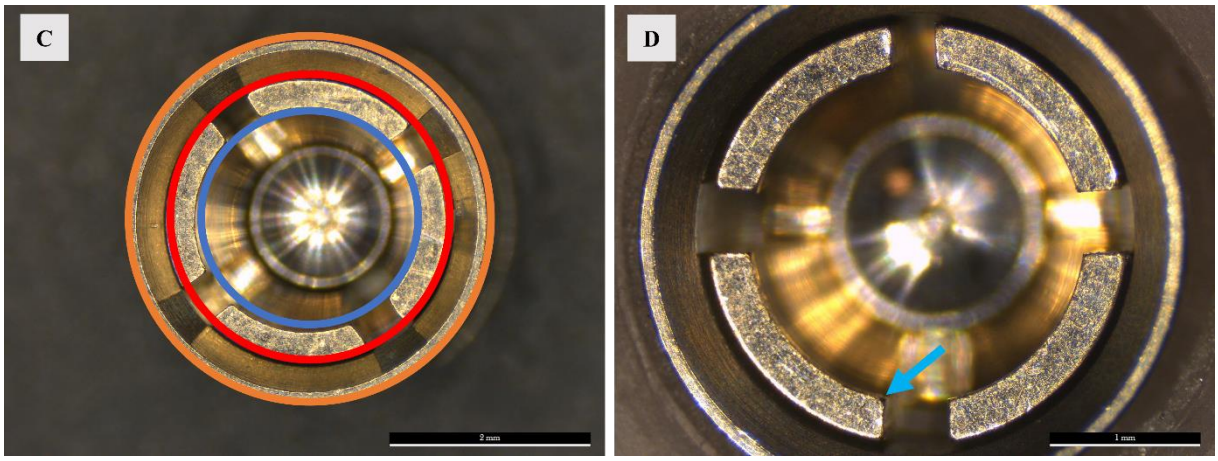


Figure 19 : Partie femelle du Ball System. (A) Neuve, exempte d'usure. (B) Usée après utilisation clinique, aplatissement des lamelles et réduction d'épaisseur du boîtier. (C) Représentation schématique des paramètres mesurés à évaluer pour l'usure quantitative : diamètre du boîtier (en orange), diamètre interne de la lamelle (en bleu), diamètre externe de la lamelle (en rouge). (D) Partie femelle B_{max} après 10000 cycles, pas de changement évident de diamètre.

4-4. Données complémentaires sur les résultats de perte de rétention

Les figures 20 à 28 montrent l'évolution de la force de rétention des échantillons de chaque SA, acquise à différents intervalles de temps au cours de la simulation (en fatigue ou en traction).

- Sur la machine de fatigue, la force maximale est enregistrée aux temps programmés sur l'ordinateur, uniquement pour les échantillons 1 (lors de la première série de test) et 5 (lors de la deuxième série de test), tous les 5 cycles (de 10 à 90), tous les 10 cycles (de 101 à 990), tous les 50 cycles (de 1001 à 9990). Elle est représentée par les points gris « Fatigue 1 » et « Fatigue 5 » sur le graphique.
- Sur la machine universelle de traction, la moyenne de 10 cycles est enregistrée, pour tous les échantillons, au début de l'expérimentation (mesure de la rétention initiale), puis à chaque arrêt du test de fatigue (à 90, 990, 4 990 et 9 990 cycles). Elle est représentée par les points colorés « Lot 1 à 8 » sur le graphique.

La comparaison de la force des échantillons 1 et 5 sur la machine de fatigue d'une part, et sur les machines de fatigue et de traction d'autre part rend compte de la complexité des essais réalisés. Elles mettent en évidence l'impact du simulateur sur la force de rétention (mesure ponctuelle ou après plusieurs cycles de fatigue) et son influence sur le comportement viscoélastique des matériaux utilisés (alliage précieux, polyéthylène et PEEK respectivement pour le Ball System, le Locator R-Tx® et le Novaloc®).

Les mesures cycliques sur le Ball System montrent parfois des résultats aberrants comme entre 10 et 1000 cycles du lot 1 pour Bmed ou ceux observés pour le lot 1 de Bmax. Lors de l'essai, le signal au cours du cycle n'est pas enregistré, seule une valeur (moyenne, minimum ou maximum sur une certaine partie du cycle) est extraite du cycle pour lequel la mesure est programmée. Il est donc impossible de vérifier les mesures a posteriori et de mieux comprendre le résultat obtenu. Nous nous attendions à un comportement cyclique variable en raison de l'écrouissage de l'alliage précieux que nous voyons davantage sur les mesures sur machine de traction que sur le simulateur de mastication.

Pour le Locator R-Tx®, les mesures sur le simulateur sont plutôt en accord avec les mesures sur la machine de traction et mettent en avant la variabilité du comportement cyclique de ce système. En effet, en plus de la diminution progressive de la rétention, une chute plus abrupte survient tardivement, à des moments variables en fonction des échantillons : par exemple, pour la gaine bleue, entre 1000 et 5000 cycles pour le lot 1 et entre 5000 et 10000 pour le lot 2. Pour ce lot 2, on note également une augmentation de la rétention après 5000 cycles avant la décroissance finale, probablement due à la viscoélasticité du matériau et non représentative du comportement en service de l'attachement.

Enfin, pour le Novaloc®, les données mesurées sur le simulateur de mastication sont plutôt en accord avec les mesures sur la machine de traction. On note quelques points où la rétention est mesurée à 0 (gaines verte et noire) ce qui peut indiquer :

- soit que le système ne se vérouillait plus à chaque cycle,
- soit que le maximum était atteint en dehors de la zone d'intérêt.

Pour quasiment toutes les gaines, on note une augmentation progressive de la rétention au cours du chargement cyclique puis un retour à un niveau de rétention plus faible après chaque arrêt pour effectuer la mesure sur la machine de traction. Ce phénomène montre de nouveau l'impact de la viscosité du matériau PEEK sur la mesure. Le matériau n'ayant pas le temps de relaxer complètement entre deux cycles, il apparaît faussement plus rigide au cours du temps. Compte tenu des nombreuses incertitudes sur les valeurs obtenues, les données en fatigue n'ont pas été présentées dans l'article.

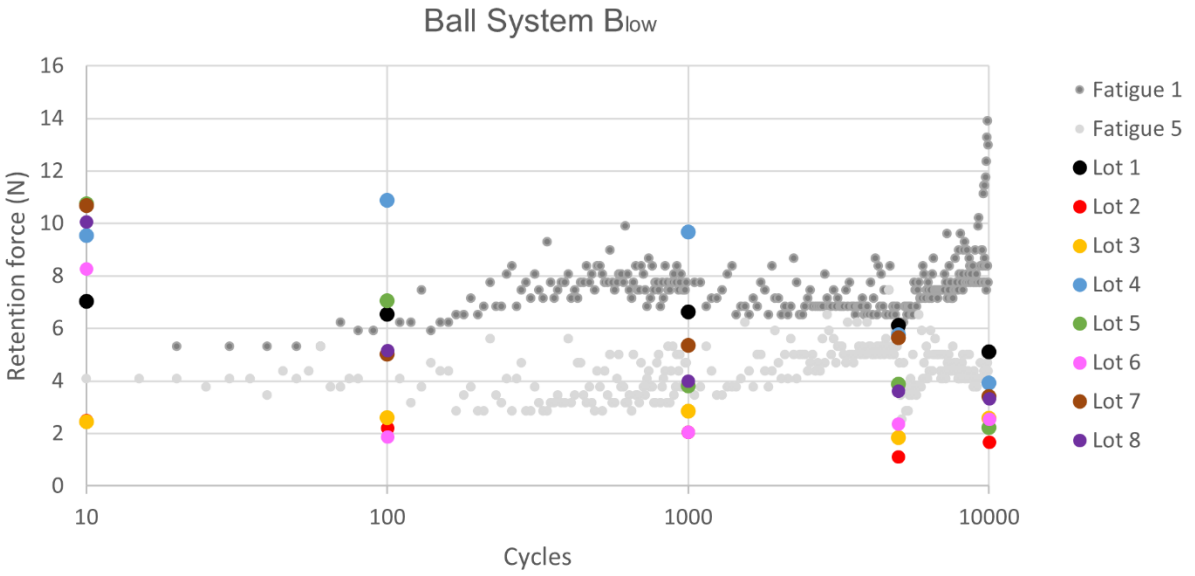


Figure 20 : Evolution de la rétention du Ball System B_{low} au cours de la simulation. L'échantillon 1 évolue de façon similaire en fatigue ou en traction jusqu'à 5 000 cycles puis le comportement diverge jusqu'à 10 000 cycles. L'échantillon 5 semble évoluer de façon similaire jusqu'à 10 000 cycles.

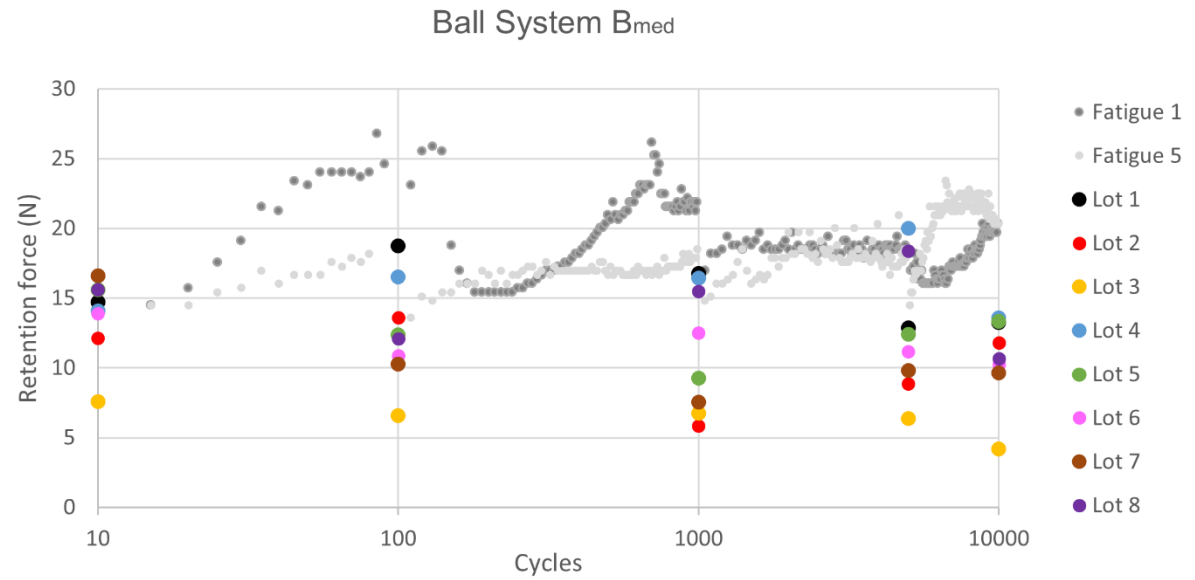


Figure 21 : Evolution de la rétention du Ball System B_{med} au cours de la simulation. Différence d'intensité de la rétention de l'échantillon 5 en fatigue ou en traction. L'intensité semble homogène en fatigue et en traction pour l'échantillon 1 jusqu'à 5 000 cycles. La rétention est étonnamment plus élevée en fatigue.

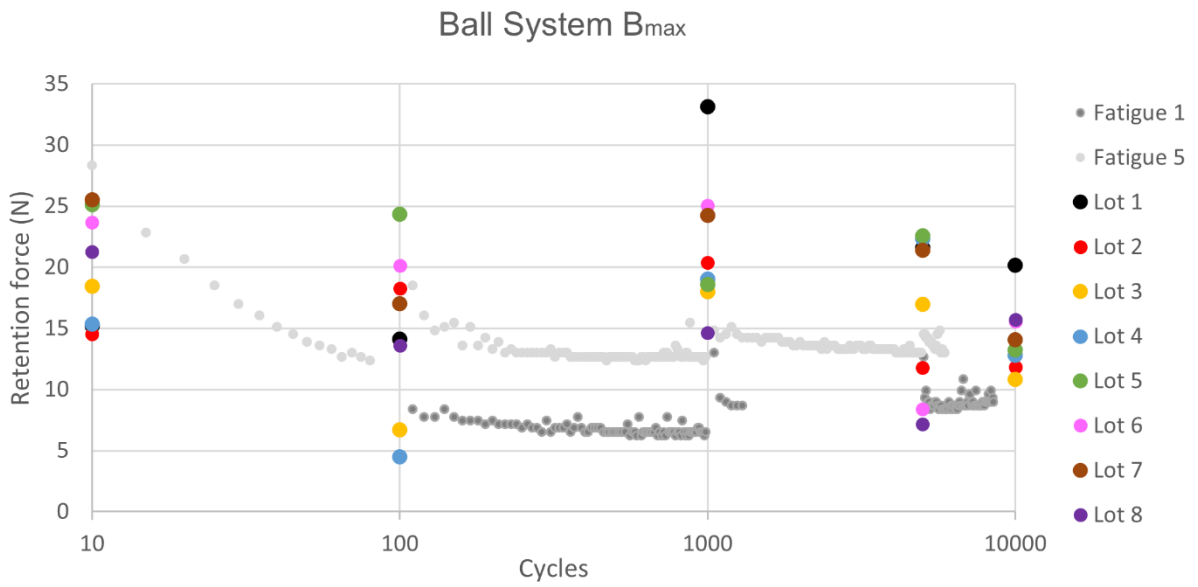


Figure 22 : Evolution de la rétention du Ball System B_{max} au cours de la simulation. L'intensité de la rétention des échantillons 1 et 5 évoluent différemment en fatigue ou en traction. La rétention est étonnamment beaucoup plus faible en fatigue.

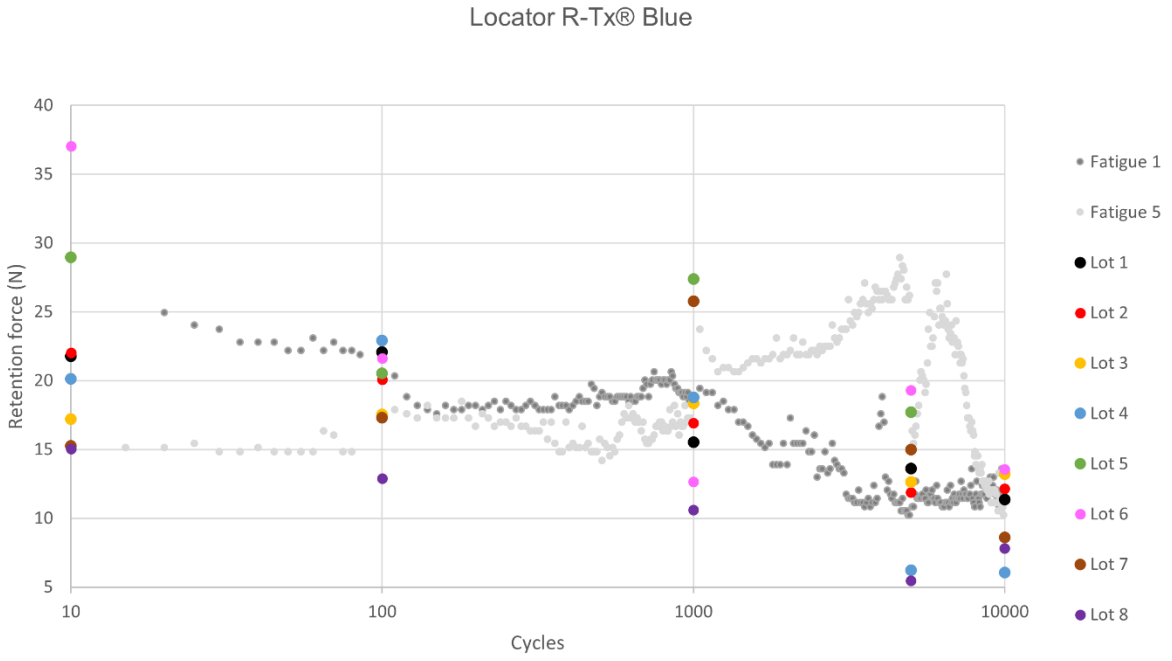


Figure 23 : Evolution de la rétention du Locator R-Tx® Blue au cours de la simulation. Différence de perte de rétention entre les échantillons 1 (à partir de 100 cycles) et 5 (à partir de 5 000 cycles). L'augmentation de la rétention de l'échantillon 5 en fatigue est probablement liée à la viscoélasticité à cause de la répétition des cycles.

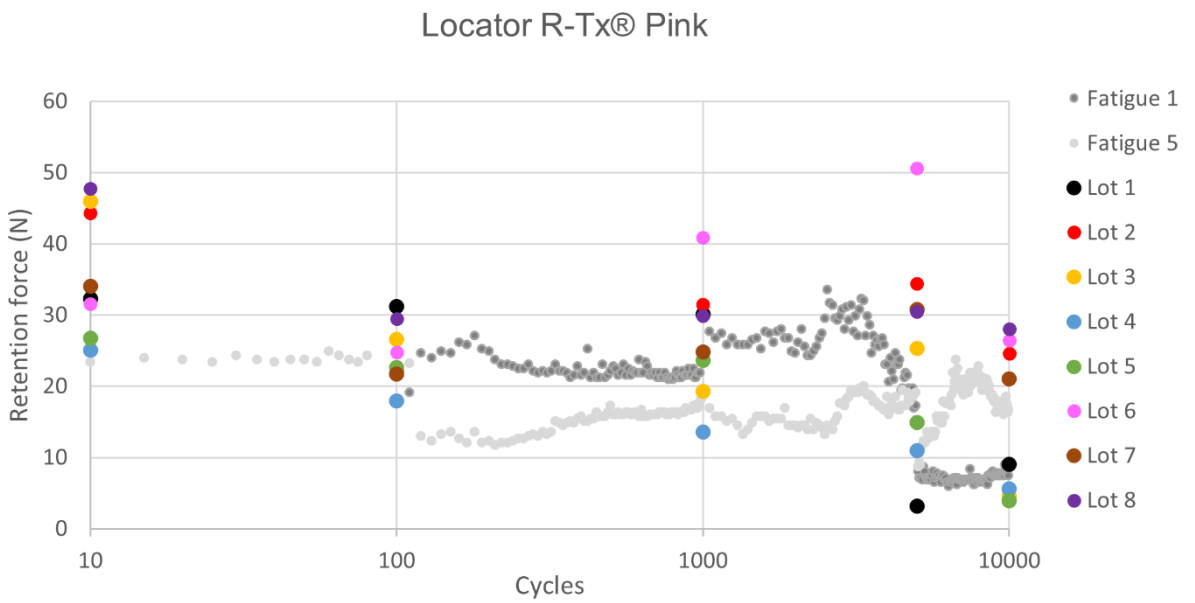


Figure 24 : Evolution de la rétention du Locator R-Tx® Pink au cours de la simulation. Chute de la rétention en fatigue à partir de 100 cycles (échantillon 5) et 5 000 cycles (échantillon 1).

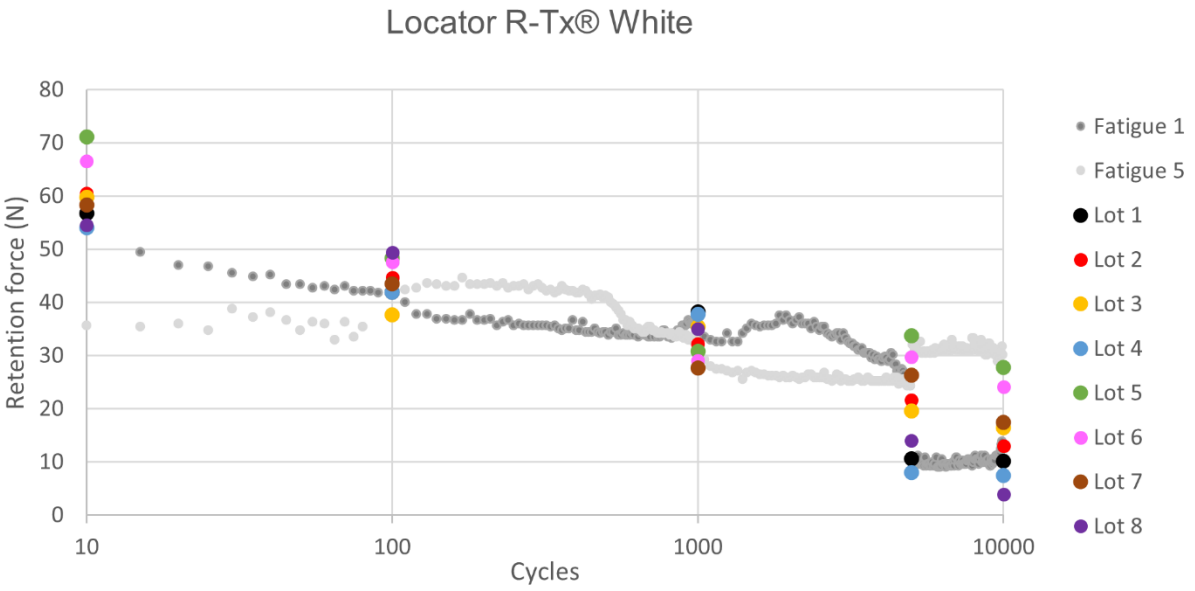


Figure 25 : Evolution de la rétention du Locator R-Tx® White au cours de la simulation. L'évolution de la perte de rétention en fatigue des échantillons est relativement similaire jusqu'à 5 000 cycles. Puis la rétention de l'échantillon 1 décroit brutalement alors que celle de l'échantillon 5 reste constante.

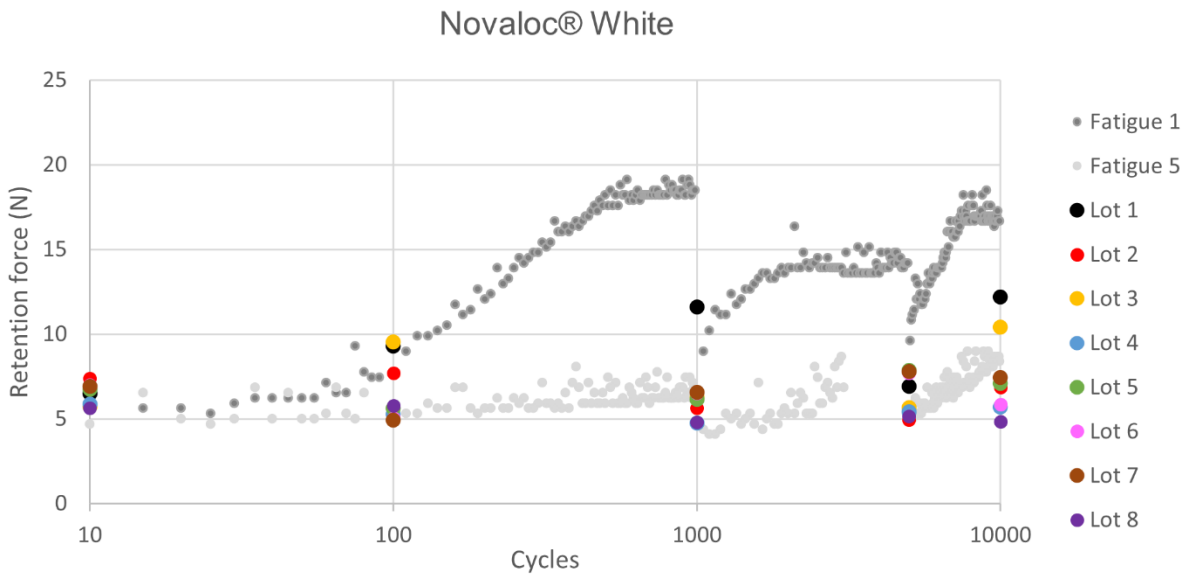


Figure 26 : Evolution de la rétention du Novaloc® White au cours de la simulation. L'intensité de la rétention évolue de façon similaire en fatigue comme en traction pour les échantillons 1 et 5. La rétention en fatigue est très différente entre les deux échantillons à partir de 100 cycles. A chaque arrêt du test de fatigue, la rétention diminue avant d'augmenter à nouveau avec la reprise de la simulation à partir de 1 000 cycles.

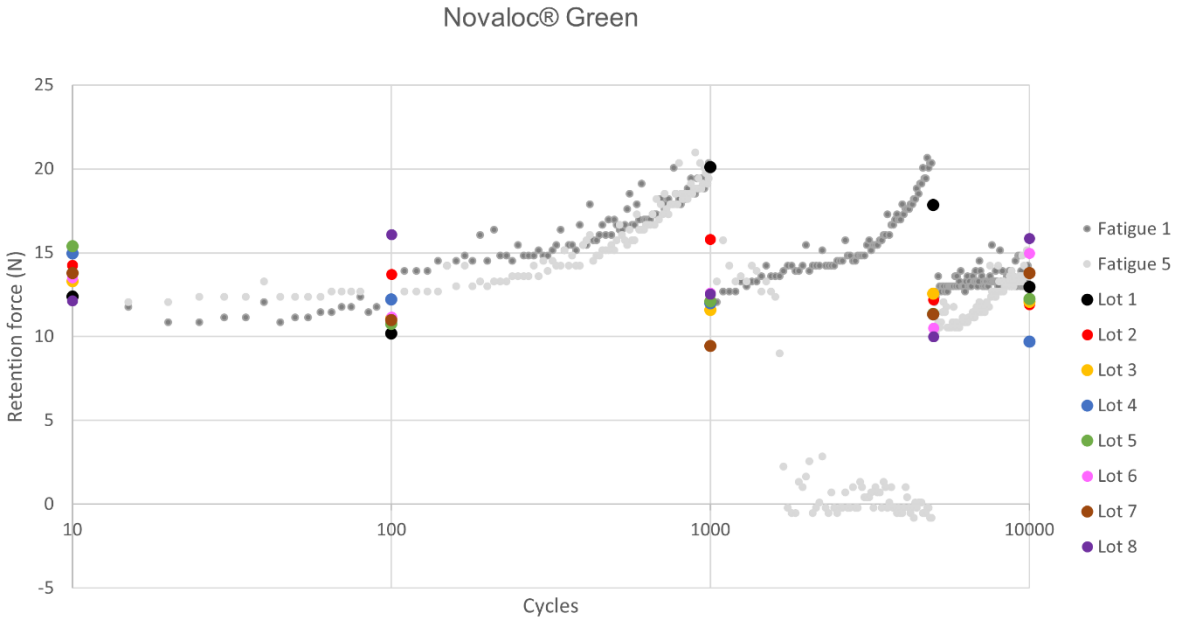


Figure 27 : Evolution de la rétention du Novaloc® Green au cours de la simulation. L'intensité de la rétention évolue de façon similaire en fatigue comme en traction pour les échantillons 1 et 5. La rétention en fatigue est plutôt identique pour les deux échantillons. A chaque arrêt du test de fatigue, la rétention diminue avant d'augmenter à nouveau avec la reprise de la simulation à partir de 1 000 cycles.

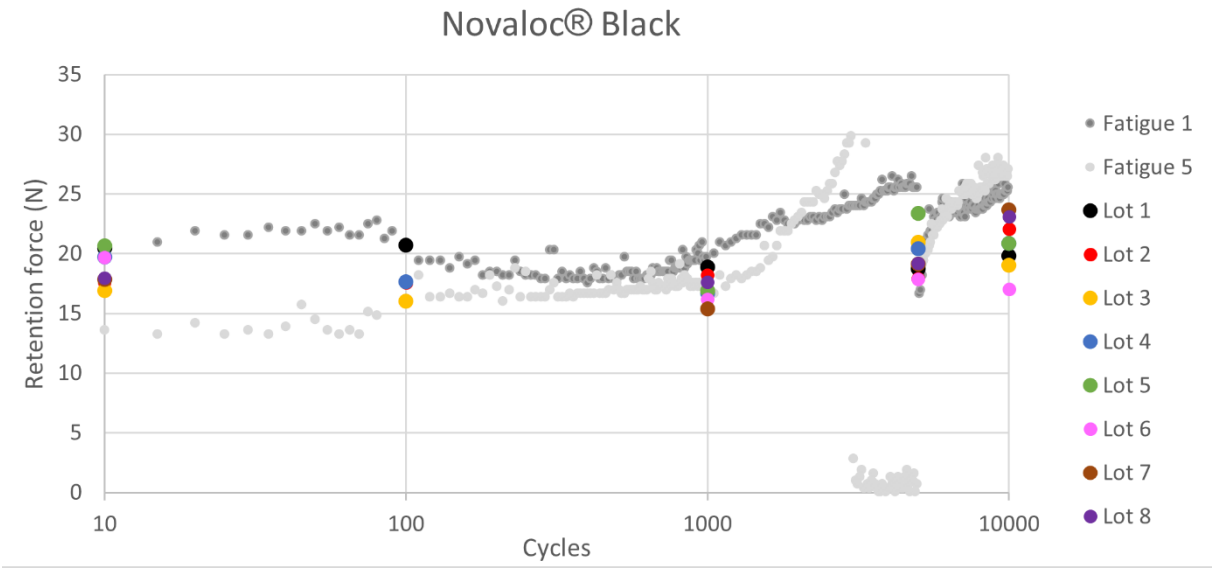


Figure 28 : Evolution de la rétention du Novaloc® Black au cours de la simulation. L'intensité de la rétention évolue de façon similaire en fatigue comme en traction pour les échantillons 1 et 5. La rétention en fatigue est plutôt identique pour les deux échantillons à partir de 100 cycles.

4-5. Données complémentaires sur les résultats d'usure du Ball System

L'évolution de l'épaisseur de la fente principale a été évaluée grâce au logiciel ImageJ® à différentes étapes de la simulation (10, 100, 1000, 5000, 10 000 CID) sur les images acquises à la loupe binoculaire (Figure 29). Il existe une petite tendance vers l'augmentation pour B_{low} et B_{med}. Mais l'analyse statistique révèle qu'il n'y a pas de différence statistiquement significative entre l'épaisseur initiale et l'épaisseur finale.

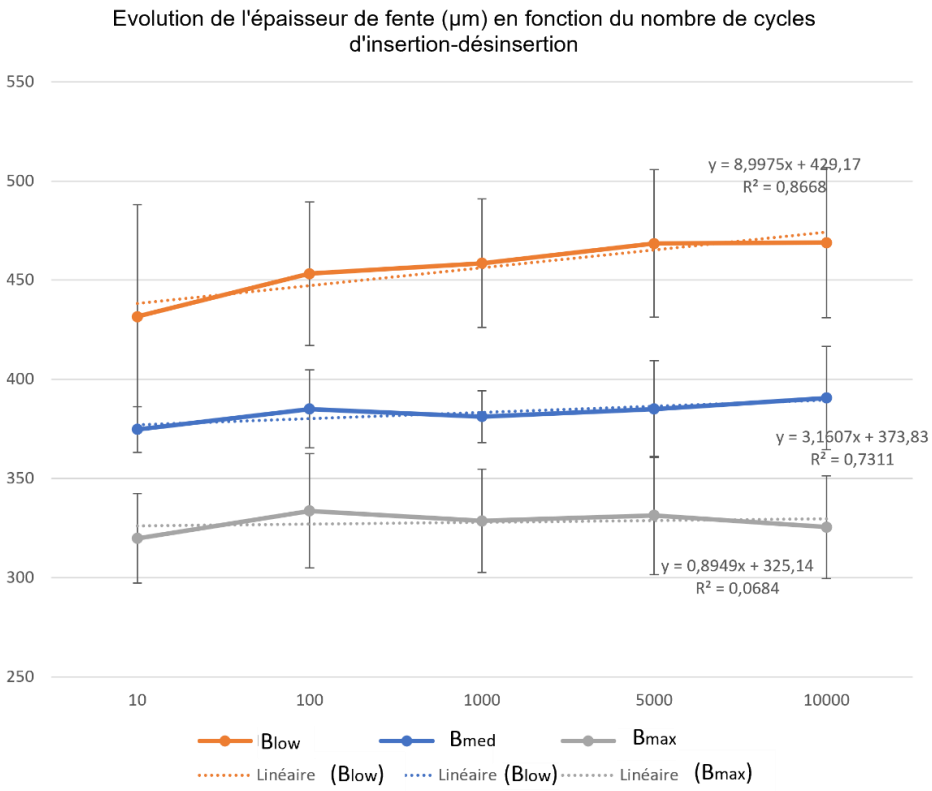


Figure 29 : Evolution de l'épaisseur de la fente principale au cours de la simulation.

L'observation des parties mâles (avant et après fixation dans le bloc à l'aide de la clé dynamométrique) ou des parties femelles (avant et après activation avec le tournevis) montrent que les outils de montage utilisés sont en partie responsables d'usure. Celle-ci concerne uniquement l'équateur du pilier boule et les extrémités ou les bords des lamelles, notamment au niveau de la fente principale (Figure 30 à 34).

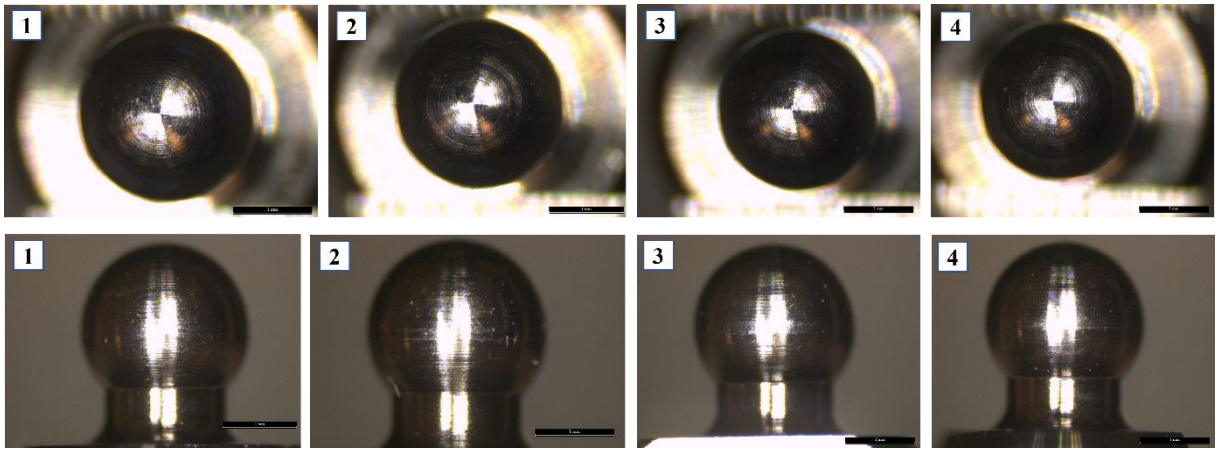


Figure 30 : Echantillons des 4 piliers boules observés à la loupe binoculaire avant le serrage à la clé dynamométrique. Absence de signe d'usure sur le sommet (1ère ligne) ou à l'équateur (2ème ligne).

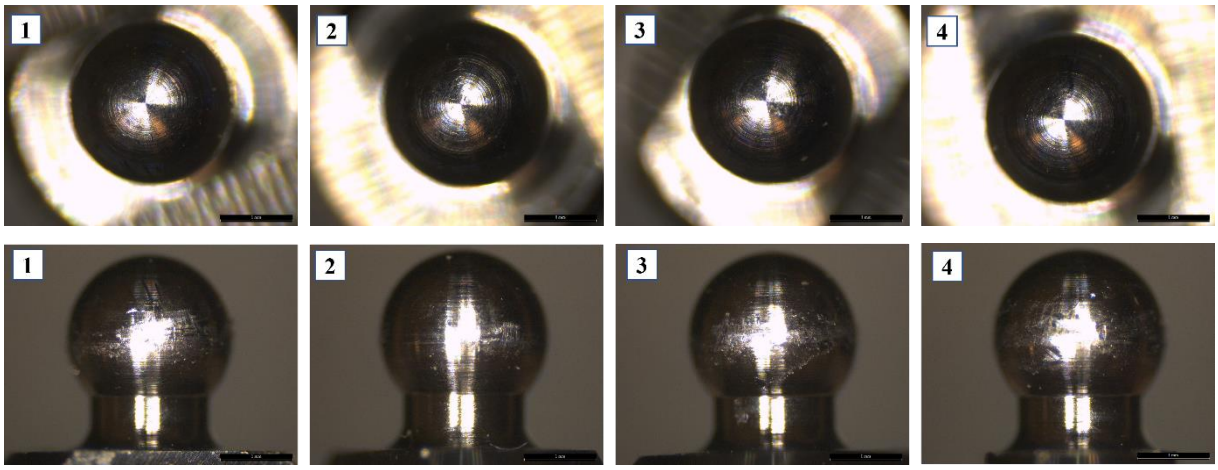


Figure 31 : Echantillons des 4 piliers boules observés à la loupe binoculaire après le serrage à la clé dynamométrique. Absence de signe d'usure sur le sommet (1ère ligne). Présence d'une bande de rayures de part et d'autre de l'équateur (2ème ligne).

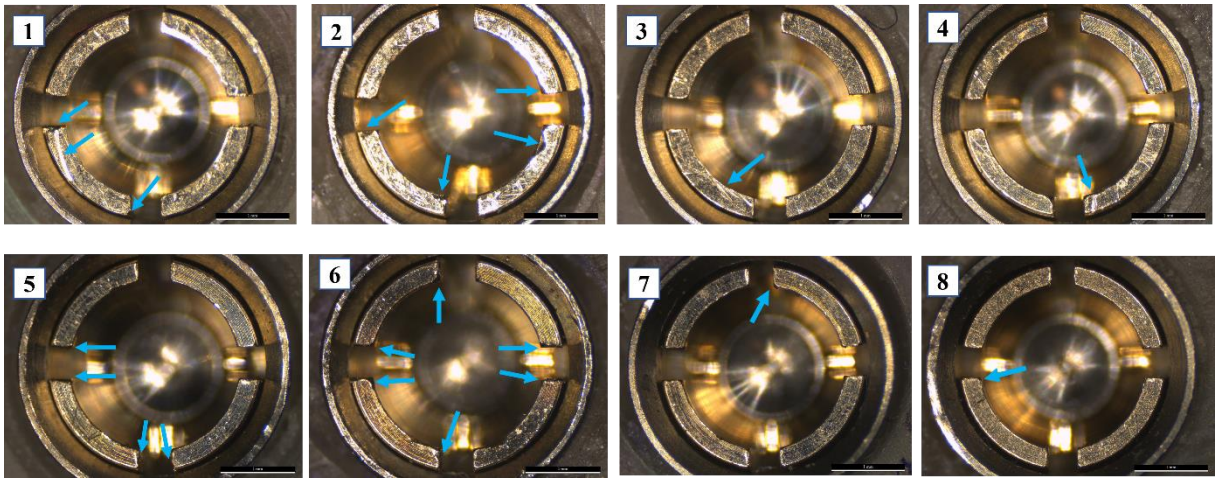


Figure 32 : Echantillons des 8 parties femelles B_{low} observés à la loupe binoculaire après le serrage à la clé dynamométrique, avant le test de fatigue. Abrasion provoquée par le tournevis d'activation visible au sommet des lamettes ou sur les bords de la fente (arrêtes émoussées).

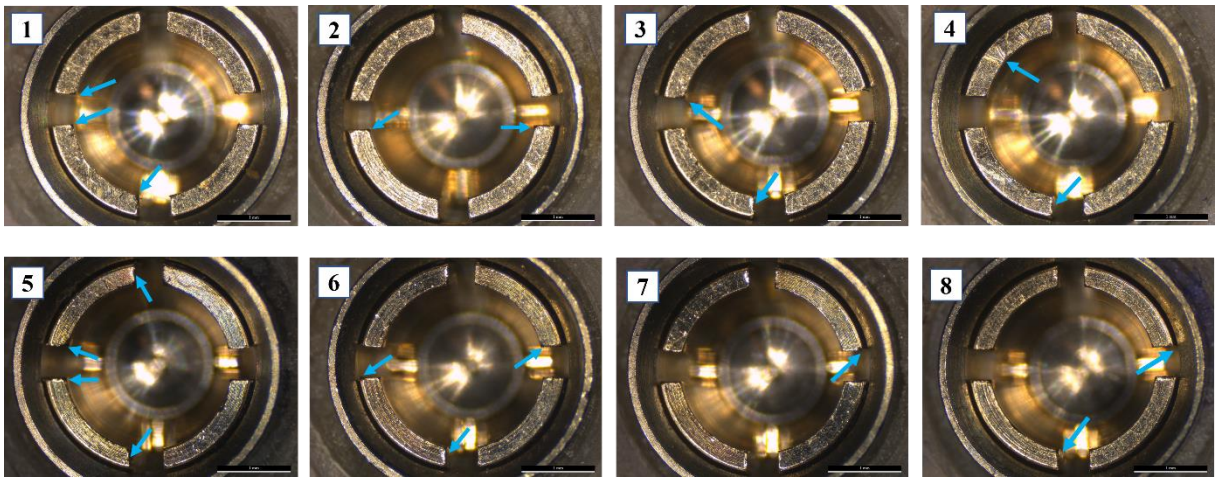


Figure 33 : Echantillons des 8 parties femelles B_{med} observés à la loupe binoculaire après le serrage à la clé dynamométrique, avant le test de fatigue. Abrasion provoquée par le tournevis d'activation visible au sommet des lamettes ou sur les bords de la fente (arrêtes émoussées).

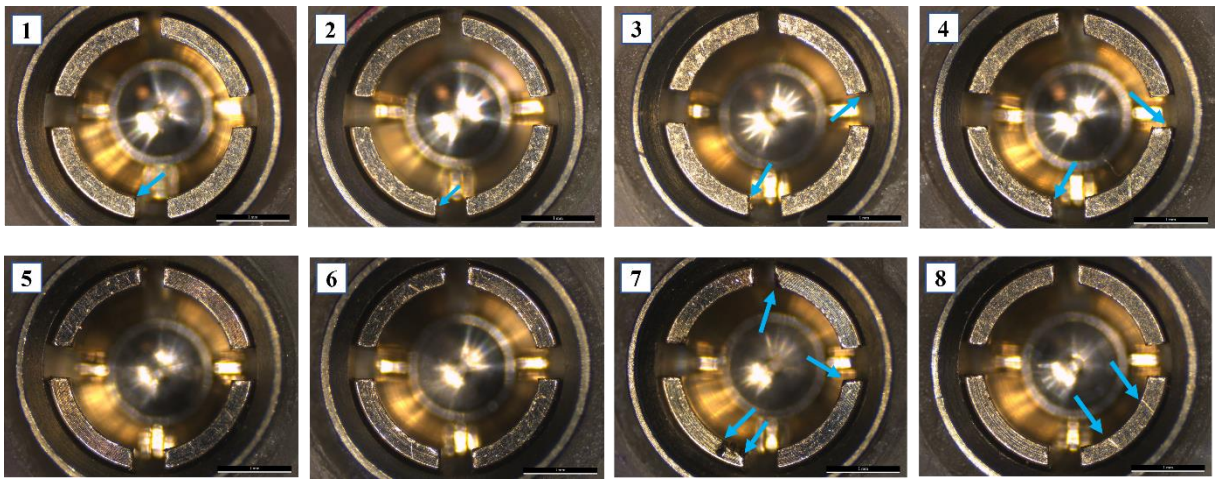


Figure 34 : Echantillons des 8 parties femelles B_{max} observés à la loupe binoculaire après le serrage à la clé dynamométrique, avant le test de fatigue. Abrasion provoquée par le tournevis d'activation visible au sommet des lamettes ou sur les bords de la fente (arrêtes émoussées).

Mais, l'usure est particulièrement liée à la fatigue, à cause des frottements de surface liés aux manoeuvres d'insertion-désinsertion. Après 10 000 CID, on note l'apparition de nouvelles traces d'usure, sans changement évident de forme ou de diamètre du pilier boule (Figures 35 à 37) ou des lamelles (Figures 38 à 40).

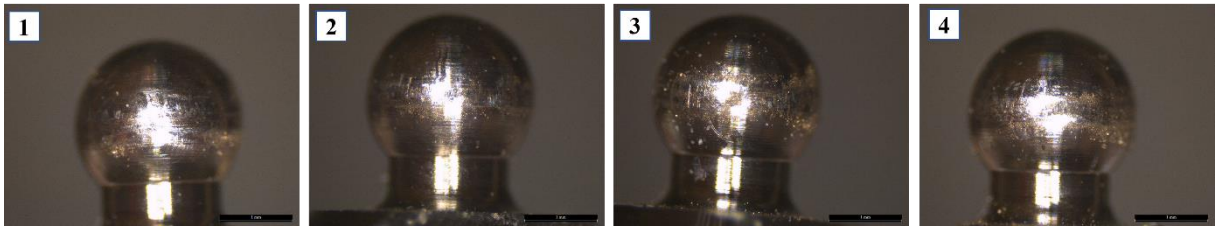


Figure 35 : Echantillons des 4 piliers boules observés à la loupe binoculaire après 10 000 cycles d'insertion-désinsertion avec les lamelles B_{low}. Présence d'une bande de rayures de part et d'autre de l'équateur.

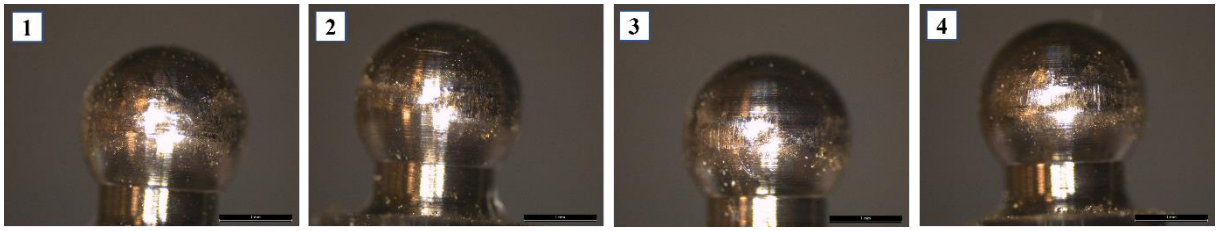


Figure 36 : Echantillons des 4 piliers boules observés à la loupe binoculaire après 10 000 cycles d'insertion-désinsertion supplémentaires avec les lamelles B_{med}. Présence d'une bande de rayures de part et d'autre de l'équateur.

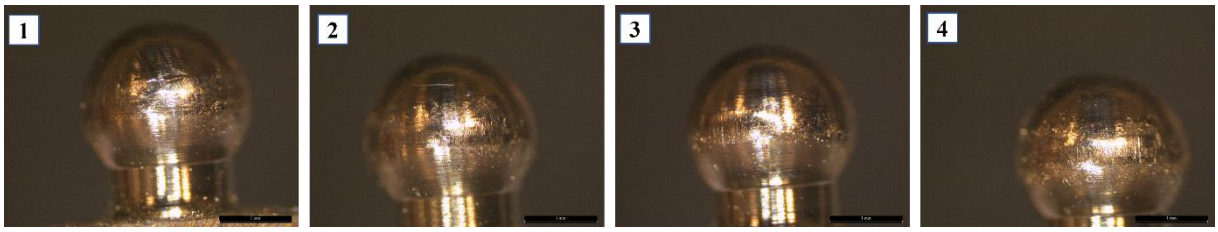


Figure 37 : Echantillons des 4 piliers boules observés à la loupe binoculaire après 10 000 cycles d'insertion-désinsertion supplémentaires avec les lamelles B_{max}. Présence d'une bande de rayures de part et d'autre de l'équateur.

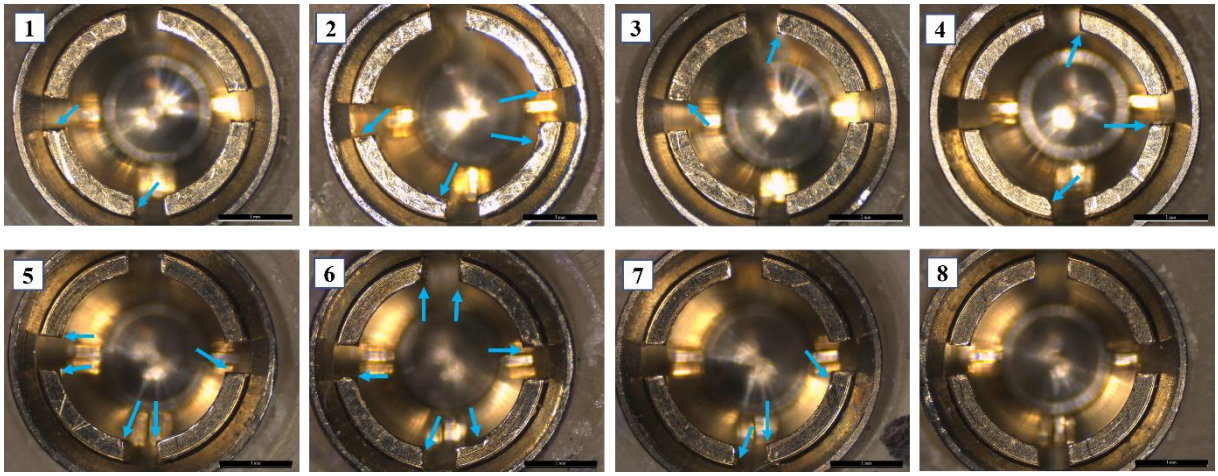


Figure 38 : Echantillons des 8 parties femelles B_{low} observés à la loupe binoculaire après 10 000 cycles d'insertion-désinsertion.

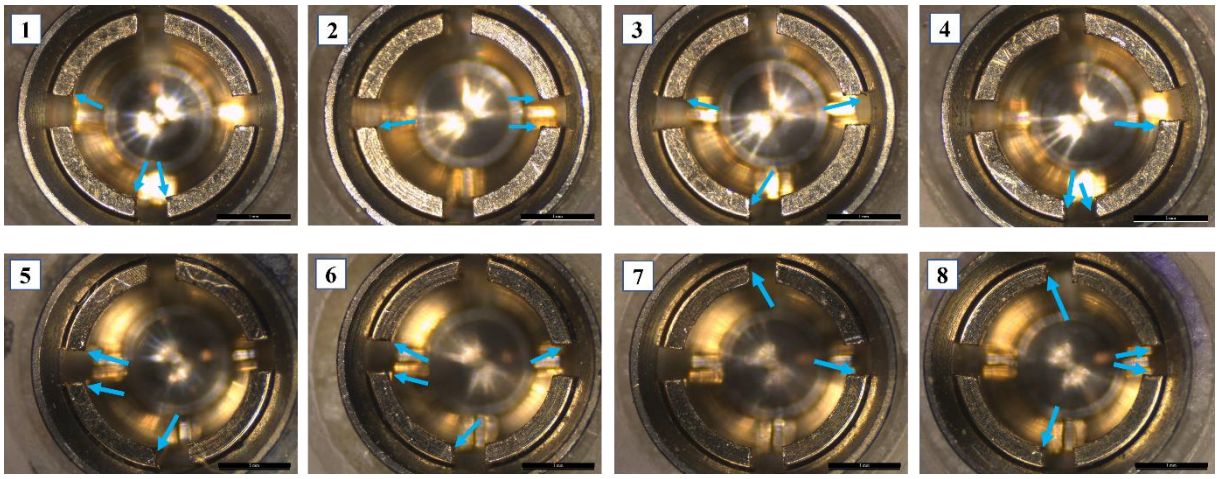


Figure 39 : Echantillons des 8 parties femelles B_{med} observés à la loupe binoculaire après 10 000 cycles d'insertion-désinsertion.

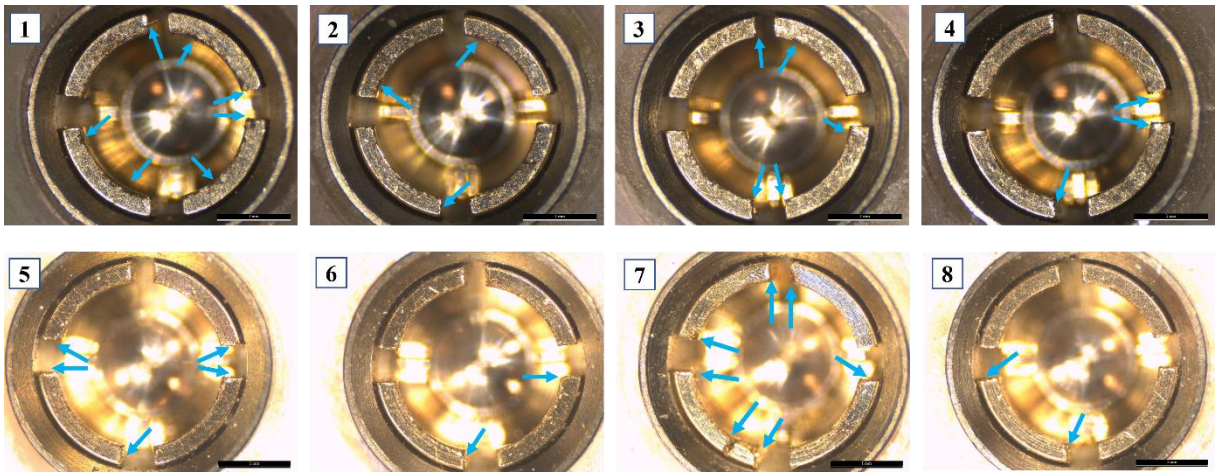


Figure 40 : Echantillons des 8 parties femelles B_{max} observés à la loupe binoculaire après 10 000 cycles d'insertion-désinsertion.

4-6. Données complémentaires sur les résultats d'usure du Locator R-Tx® et du Novaloc®

Une analyse à la loupe binoculaire montre que les piliers Locator R-Tx® ou Novaloc® sont exempts d'usure (Figures 41 et 42). L'exploitation des images 3D des parties femelles, reconstruites à partir des coupes issues du micro-CT montre que l'usure des parties femelles du Locator R-Tx® se produit à l'intérieur du DR (Figures 43 à 48) : perte de substance, délabrement des cercles concentriques en contre-dépouille, dépôt de matériau sur les bords… En ce qui concerne les parties femelles du Novaloc® (Figures 49 à 54), aucune usure particulière n'a été mise en évidence.

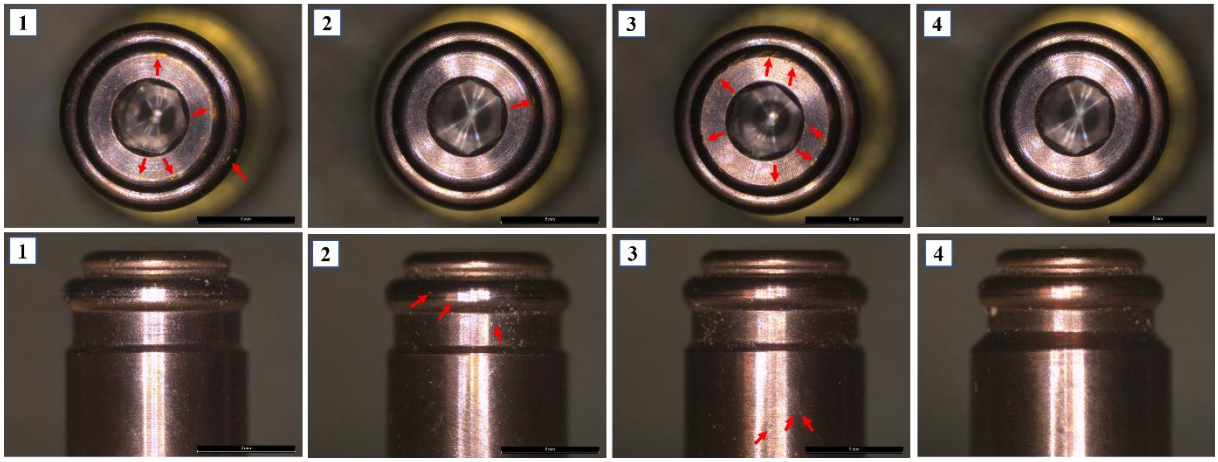


Figure 41 : Echantillons des 4 piliers Locator R-Tx® observés à la loupe binoculaire après 30 000 cycles d'insertion-désinsertion. Sommet (1ère ligne) et paroi (2ème ligne). Présence de traces sporadiques d'abrasion de la couche superficielle de résistance à l'usure TiN (titanium nitride) (flèches rouges).

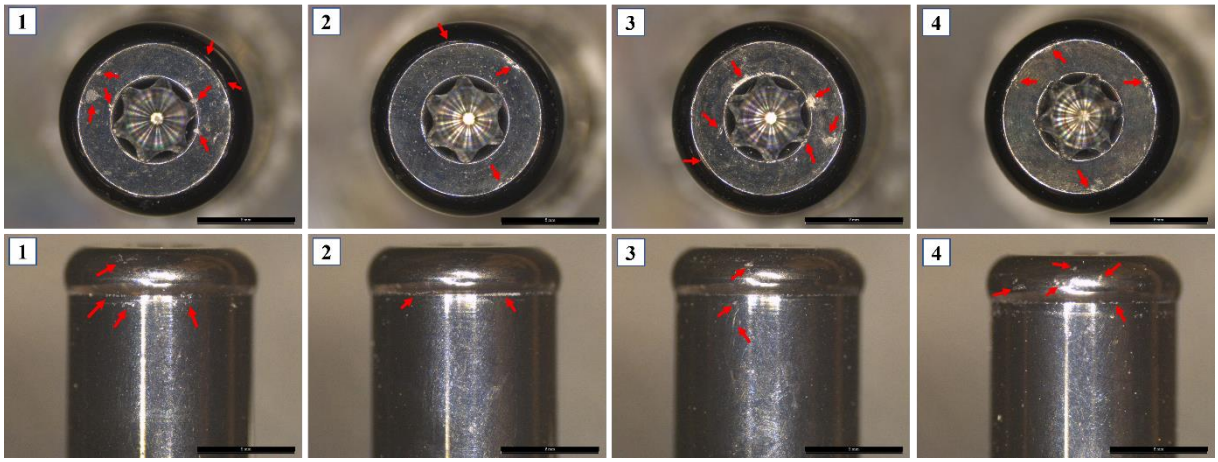


Figure 42 : Echantillons des 4 piliers Novaloc® observés à la loupe binoculaire après 30 000 cycles d'insertion-désinsertion. Sommet (1ère ligne) et paroi (2ème ligne). Présence de traces sporadiques d'abrasion de la couche superficielle de résistance à l'usure ADLC (amorphous diamond-like carbon) (flèches rouges).

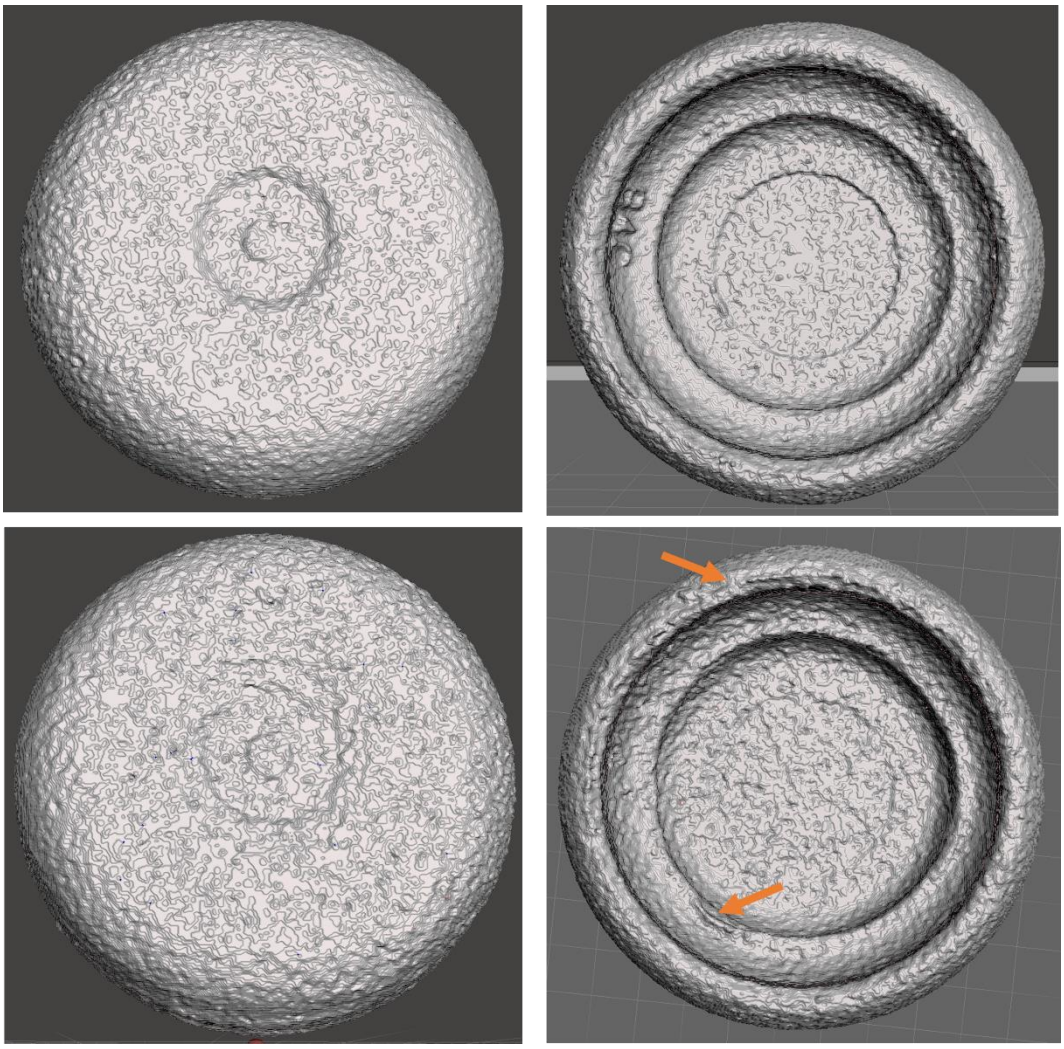


Figure 43 : Echantillon du Locator R-Tx® Blue observé avec le logiciel Meshmixer®. Images avant la simulation (1ère ligne) et après 10 000 cycles d'insertion-désinsertion (2ème ligne).

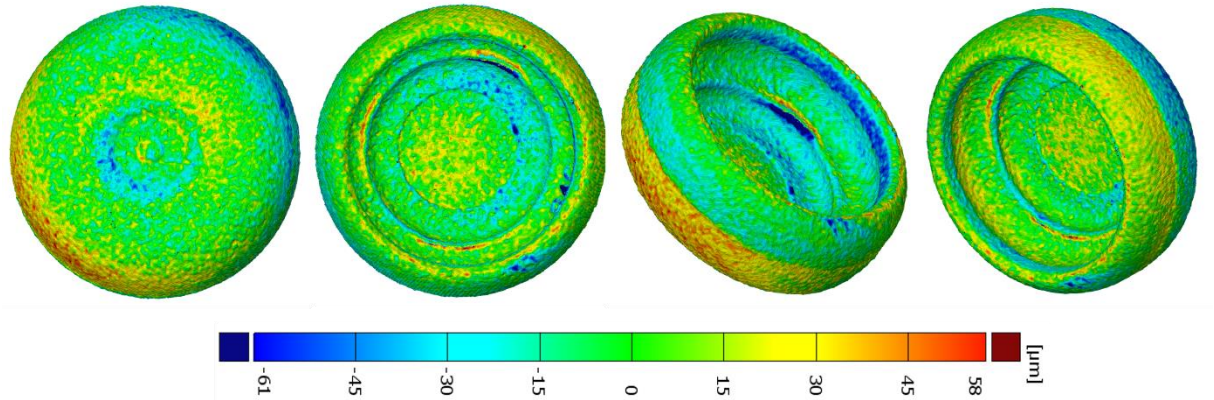


Figure 44 : Reconstruction de la déformation de l'échantillon du Locator R-Tx® Blue à l'aide du logiciel CTan® après 10 000 cycles d'insertion désinsertion.

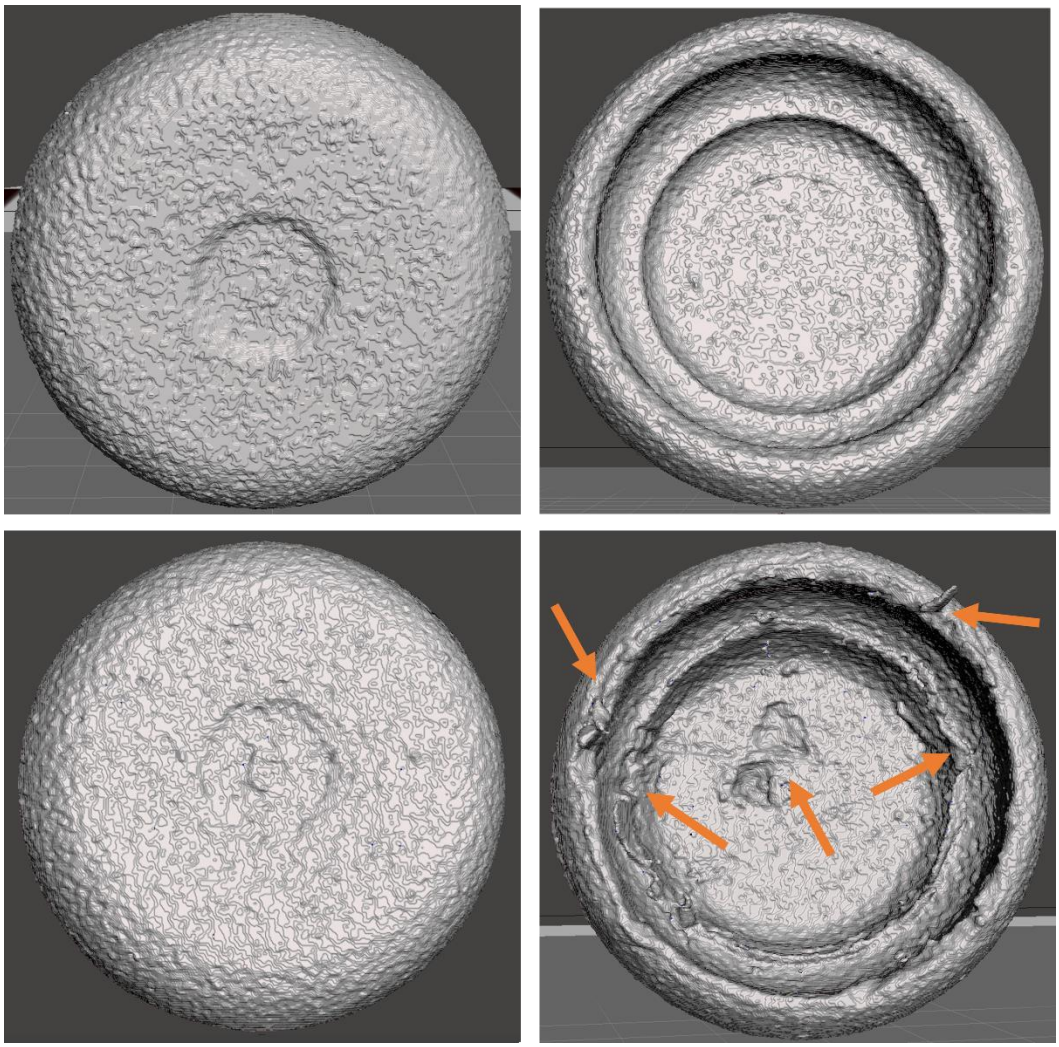


Figure 45 : Echantillon du Locator R-Tx® Pink observé avec le logiciel Meshmixer®. Images avant la simulation (1ère ligne) et après 10 000 cycles d'insertion-désinsertion (2ème ligne).

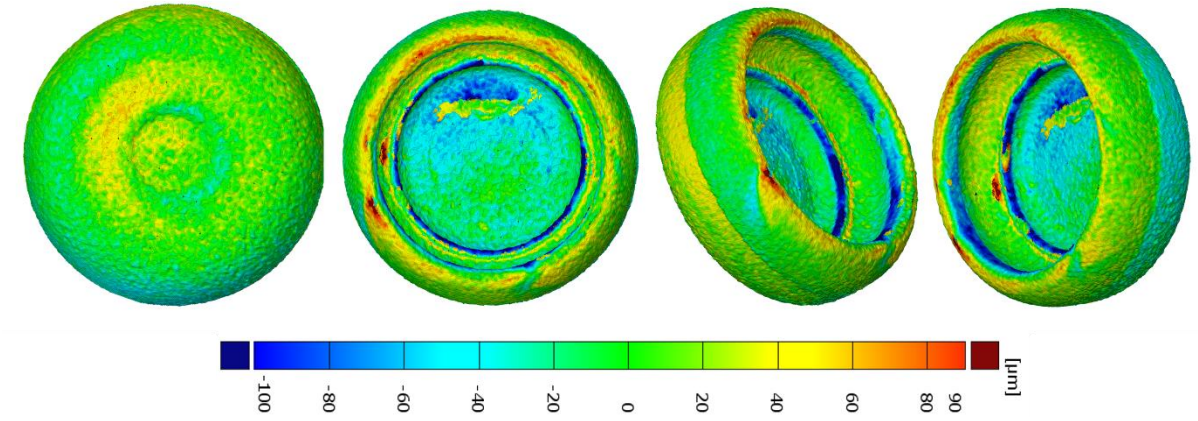


Figure 46 : Reconstruction de la déformation de l'échantillon du Locator R-Tx® Pink à l'aide du logiciel CTan® après 10 000 cycles d'insertion-désinsertion.

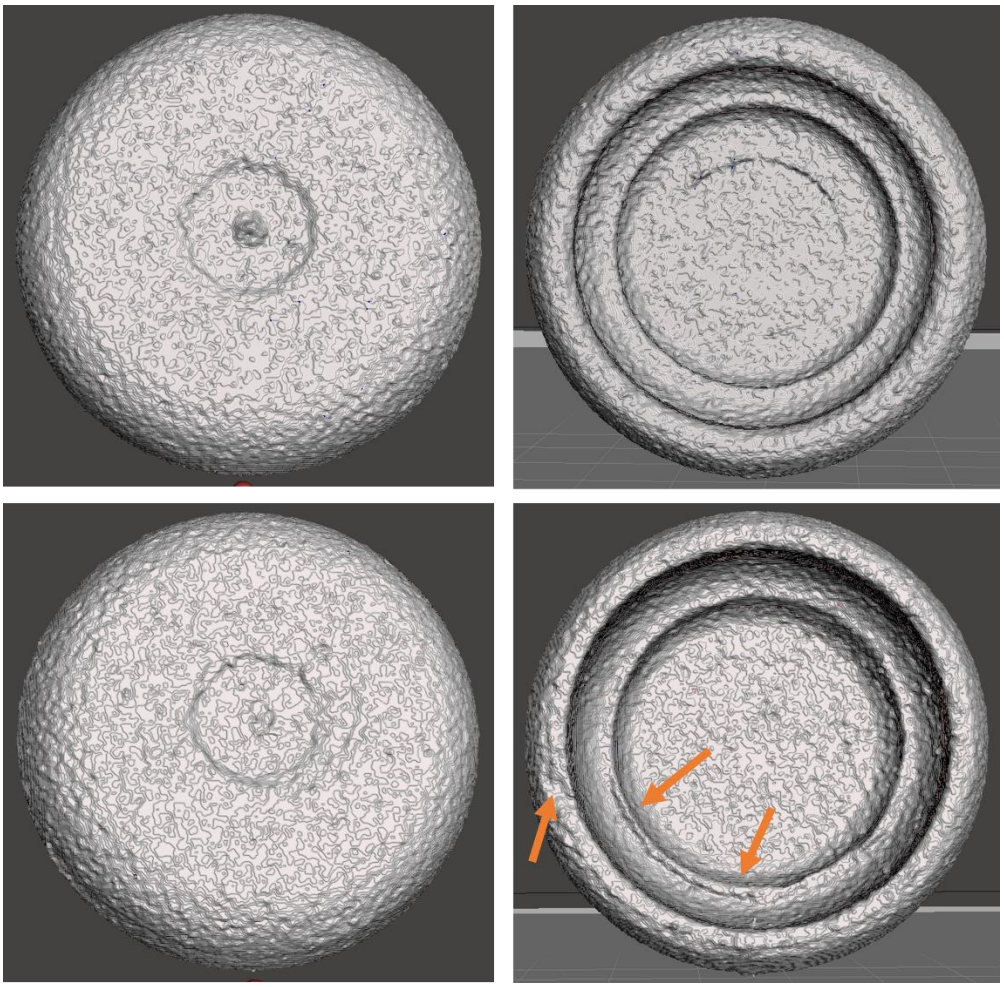


Figure 47 : Echantillon du Locator R-Tx® White observé avec le logiciel Meshmixer®. Images avant la simulation (1ère ligne) et après 10 000 cycles d'insertion-désinsertion (2ème ligne).

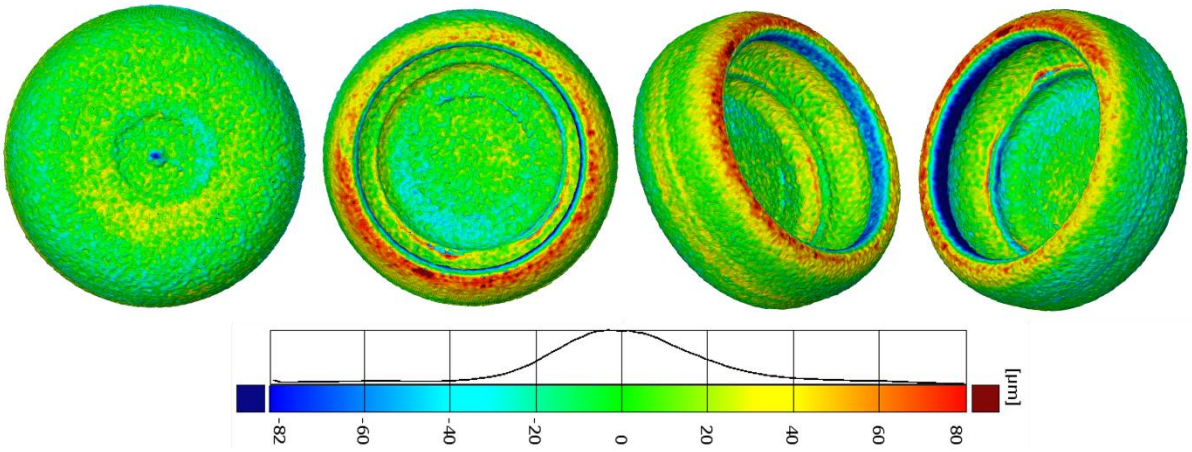


Figure 48 : Reconstruction de la déformation de l'échantillon du Locator R-Tx® White à l'aide du logiciel CTan® après 10 000 cycles d'insertion désinsertion

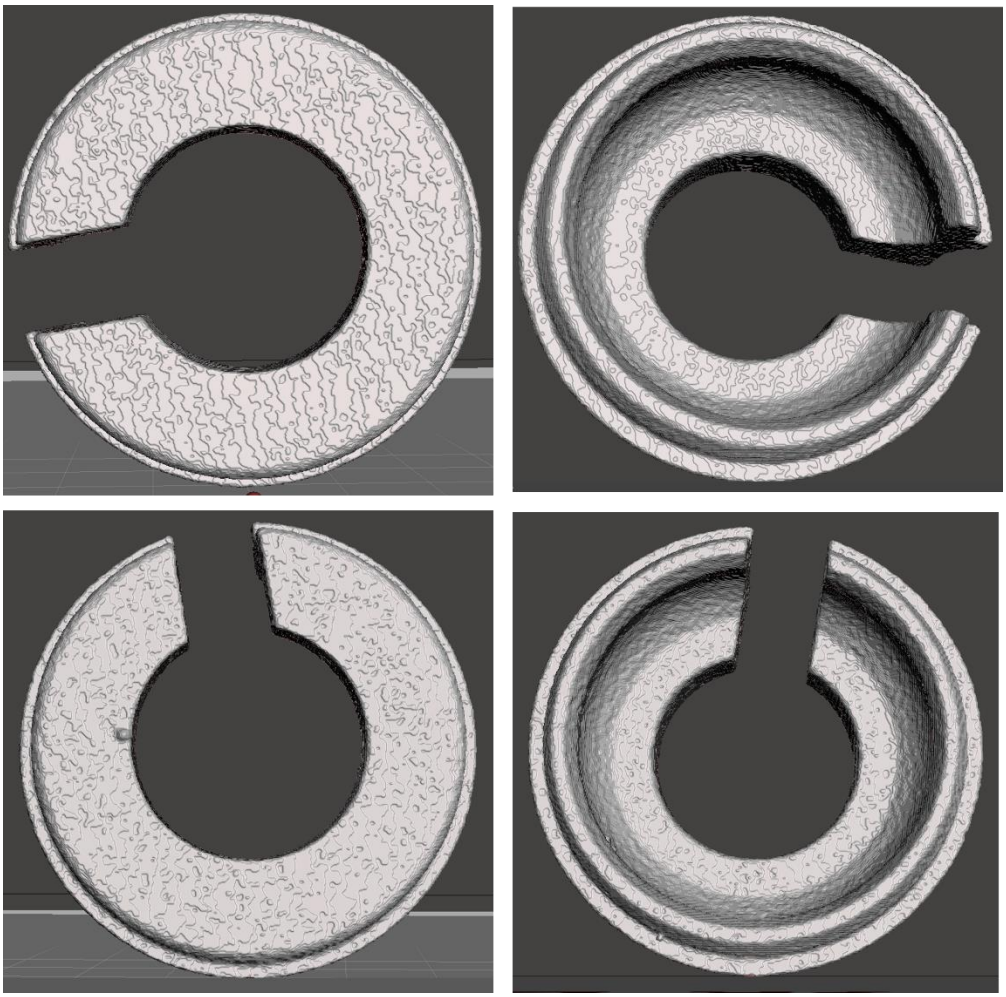


Figure 49 : Echantillon du Novaloc® Green observé avec le logiciel Meshmixer®. Images avant la simulation (1ère ligne) et après 10 000 cycles d'insertion-désinsertion (2ème ligne).

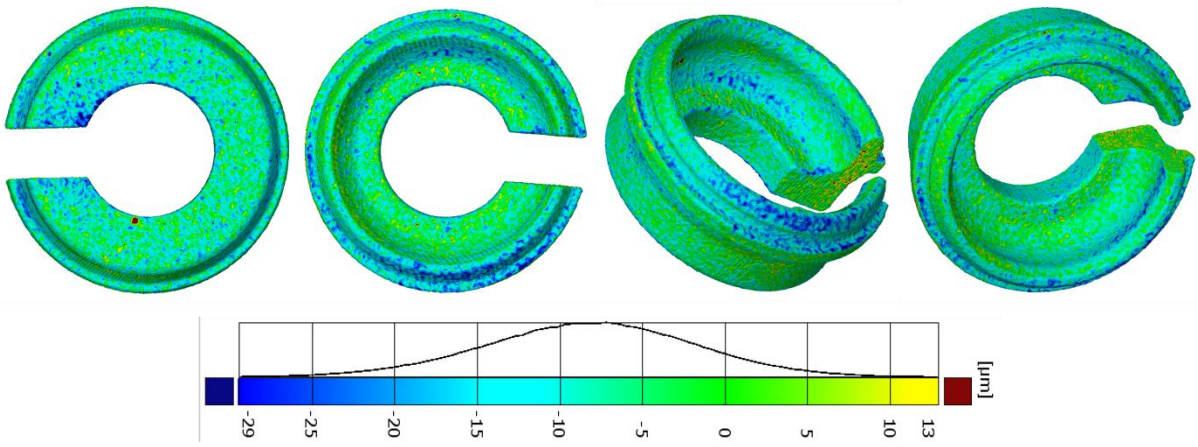


Figure 50 : Reconstruction de la déformation de l'échantillon du Novaloc® Green à l'aide du logiciel CTan® après 10 000 cycles d'insertion désinsertion.

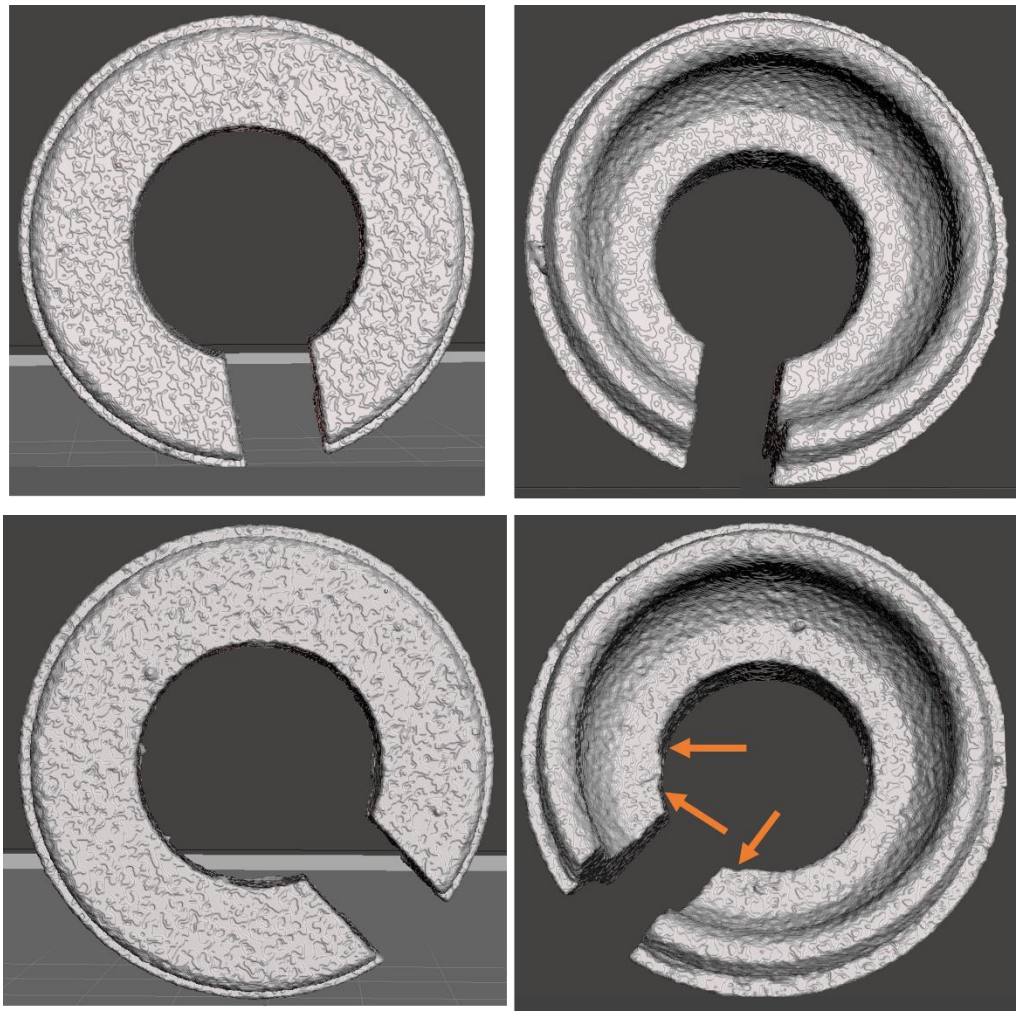


Figure 51 : Echantillon du Novaloc® Black observé avec le logiciel Meshmixer®. Images avant la simulation (1ère ligne) et après 10 000 cycles d'insertion-désinsertion (2ème ligne).

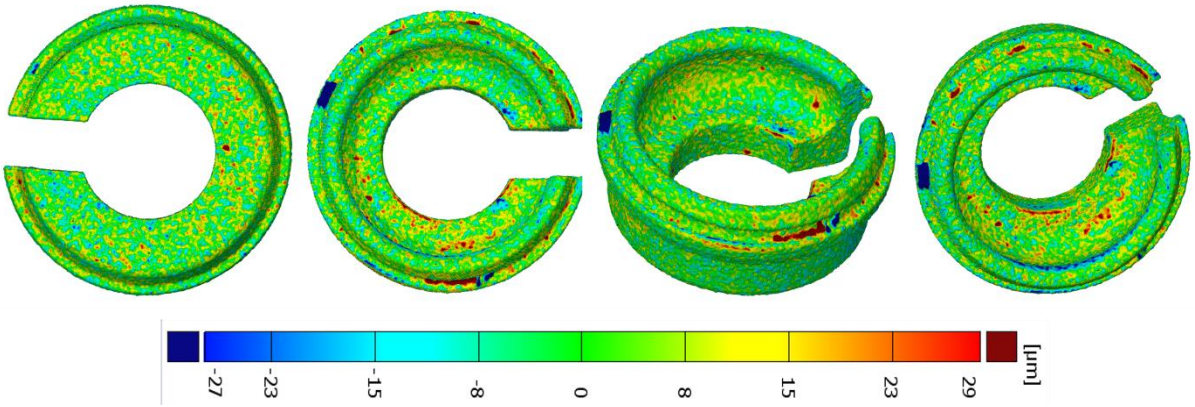


Figure 52 : Reconstruction de la déformation de l'échantillon du Novaloc® Black à l'aide du logiciel CTan® après 10 000 cycles d'insertion désinsertion.

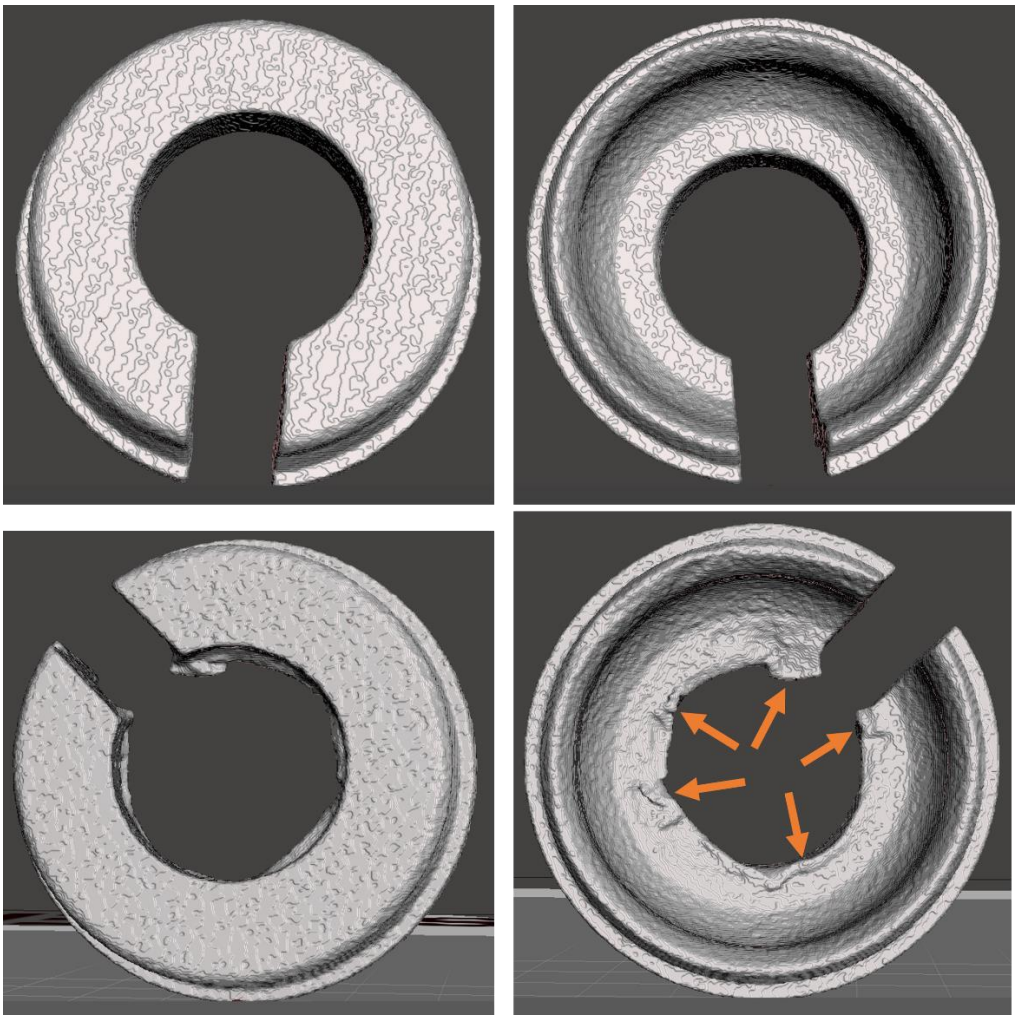


Figure 53 : Echantillon du Novaloc® White observé avec le logiciel Meshmixer®. Images avant la simulation (1ère ligne) et après 10 000 cycles d'insertion-désinsertion (2ème ligne).

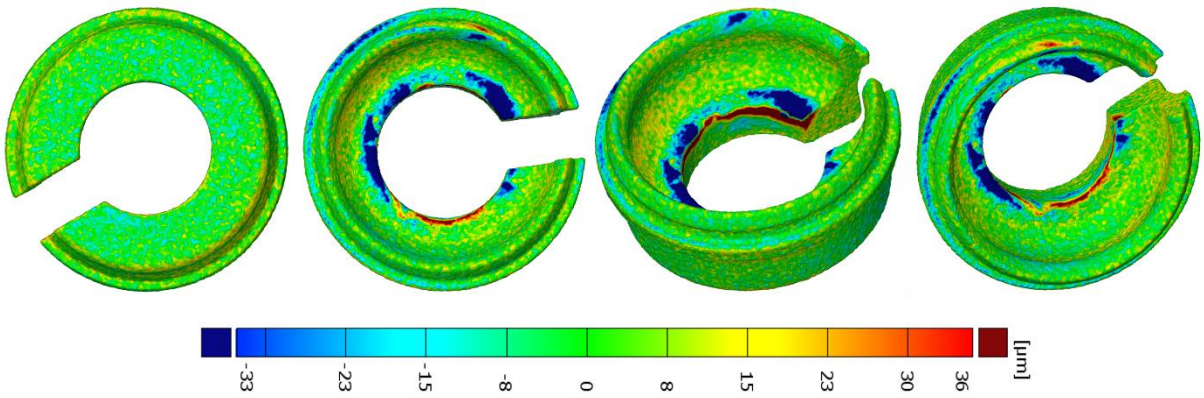


Figure 54 : Reconstruction de la déformation de l'échantillon du Novaloc® White à l'aide du logiciel CTan® après 10 000 cycles d'insertion-désinsertion.

Conclusion Générale

Ce travail de thèse s'est intéressé à la prothèse amovible complète mandibulaire (PACM) retenue sur 1 ou 2 implants grâce à différents systèmes d'attachements (SA) axiaux unitaires supra-implantaires, de type boule (SAB) ou cylindrique (SAC). Notre choix s'est porté sur le Ball System, système de référence le plus évalué dans la littérature, et les nouveaux systèmes cylindriques Locator R-Tx® et Novaloc® apparus dans les années 2010, promus par les fabricants comme ayant une meilleur rétention et une meilleure résistance à l'usure, et ainsi une réduction des besoins en maintenance.

Cette thèse a permis dans un premier temps une analyse de la littérature via une revue systématique afin de dresser un état des lieux de l'ensemble des études comparant les SAB et les SAC du point de vue de leur rétention initiale, de leur perte de rétention dans le temps, de l'usure, et de leur besoin de maintenance clinique. Cette analyse a permis la construction d'un protocole de recherche avec la mise au point d'un dispositif expérimental *in vitro* simulant une PACM retenue sur 1 implant, ce dispositif devant permettre d'évaluer la rétention initiale aussi bien pour un SAB (Ball System) que pour les deux SAC sélectionnés (Locator R-Tx® et Novaloc®). Cette étude a conduit à une évaluation de la rétention initiale des différents dispositifs et la comparaison intra et inter-système de ces trois SA. Dans un second temps cette étude a été complétée par l'évaluation de leur perte de rétention dans le temps avec une mesure de la rétention finale à 10 000 cycles et une analyse de leur usure.

Les résultats de nos travaux montrent que :

- la force de rétention initiale du SAC est supérieure à celle du SAB. La rétention initiale est significativement plus élevée pour le Locator R-Tx® que pour le Ball System et le Novaloc®. Les valeurs de rétention obtenues semblent suffisantes pour satisfaire le patient (> 5N) pour une PACM retenue sur 1 implant, sauf pour les DR Novaloc® Red et Locator R-Tx® Gray.
- la perte de rétention dans le temps concerne tous les SA. Le Novaloc® semble mieux résister à la fatigue que le Ball System et le Locator R-Tx®. L'usure du SA affecte particulièrement les parties femelles. Le facteur mécanique (insertion-désinsertion, mastication) est considéré comme le principal paramètre d'usure et de perte de rétention. Le pilier du Ball System présente une usure à l'équateur sans changement évident de diamètre, les lamelles métalliques ont une usure discrête à modérée (rayures, arêtes

émoussées). Les piliers du Locator R-Tx® et du Novaloc® sont intacts, le dispositif de rétention en plastique du Locator R-Tx® s'use beaucoup plus que celui du Novaloc®.

- l'usure est présente quel que soit le SA, associé à la perte de rétention, ces deux paramètres doivent être pris en compte sur le besoin en maintenance.

Considérant les paramètres évalués, le choix du SA va également dépendre des besoins spécifiques de chaque patient et de la situation clinique : SAB si une rétention initiale faible et plus durable dans le temps est souhaitée ; CAS si une rétention plus ou moins élevée est recherchée avec pour le Locator R-Tx® la rétention intitiale disponible la plus élevée mais une usure importante expliquant une perte de rétention rapide et donc un changement des DR plus fréquent.

L'observation de l'usure des lamelles du système boule en situation clinique (Figure 29B), montre une forte abrasion de celles-ci, contrairement à nos observations *in vitro*. Le modèle simulé de PACM retenue sur 1 implant ne peut malheureusement pas rendre compte de la complexité des mécanismes d'usure des SA qui interviennent cliniquement, notamment sous l'action des forces de mastication. De plus, des études complémentaires sont nécessaires pour analyser l'influence de l'angulation implantaire, du nombre d'implants, de l'angulation inter-implantaire, de l'angulation du DR par rapport à l'axe d'insertion sur l'évolution de la force de rétention et l'usure de ces 3 SA au cours du temps. Ces informations permettraient d'aider le chirurgien-dentiste à choisir en fonction du cahier des charges de chaque situation clinique pour anticiper au mieux les futurs besoins en maintenance de ses SA.

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RÉSUMÉ

Les systèmes d'attachements (SA) axiaux unitaires supra-implantaires améliorent la rétention et la stabilité des prothèses amovibles complètes mandibulaires retenues (PACR) sur 1 à 4 implants, 2 implants étant la norme. Une revue systématique de la littérature réunissant les études cliniques et *in vitro* comparant les SA boules (SAB) et cylindriques (SAC) a montré que les SAC ont une meilleure rétention initiale mais que cet avantage diminue avec le temps et l'usure. Pour répondre au manque de standardisation identifié dans les études *in vitro*, un protocole expérimental est développé pour caractériser la rétention et l'usure d'un SAB (Ball System) et de deux SAC (Locator R-Tx® et Novaloc®) en contrôlant l'orientation de l'axe d'insertion-désinsertion. Bien qu'offrant une gamme plus large de rétention initiale, le Locator R-Tx® présente la perte de rétention la plus importante, corrélée à l'usure observée sur son dispositif de rétention (DR), conduisant à une rétention finale comparable aux autres systèmes après 10 000 cycles d'insertion-désinsertion (CID). Le Ball System présente une rétention variable dans le temps tandis que la rétention du Novaloc® est stable. La rétention finale semble suffisante et dans la limite de rétention acceptée par le patient pour une PACM retenue sur 1 implant après 10 000 CID, sauf pour le DR le plus faible du Ball System. Même si les schémas d'usure varient cliniquement pour chaque patient, un besoin de maintenance plus fréquent est attendu pour le Locator R-Tx®. Des études complémentaires seront nécessaires pour comprendre l'influence des paramètres prothétiques sur la rétention et l'usure.

ABSTRACT

Unsplinted attachment systems (AS) improve the retention and stability of implant retained mandibular overdentures (IRMO) on 1 to 4 implants, with 2 implants being the standard of care. A systematic literature review of clinical and *in vitro* studies comparing ball (BAS) and cylindrical (CAS) AS showed that CAS have better initial retention but that this advantage decreases with time and wear. To address the lack of standardization identified in *in vitro* studies, an experimental protocol is developed to characterize the retention and wear of one SAB (Ball System) and two SAC (Locator R-Tx® and Novaloc®) by controlling the orientation of the insertion-removal axis. Although offering a wider range of initial retention, the Locator R-Tx® has the highest retention loss, correlated to the wear observed on its retention device (DR), leading to a final retention comparable to the other systems after 10,000 insertion-removal cycles (IRC). The Ball System shows a variable retention over time while the Novaloc® retention is stable. Final retention appears to be sufficient and within the patient-accepted retention limit for a PACM retained on 1 implant after 10,000 IRC, except for the lowest DR of the Ball System. Although wear patterns vary clinically for each patient, a more frequent need for maintenance is expected for the Locator R-Tx®. Further studies are needed to understand the influence of prosthetic parameters on retention and wear.