UNIVERSITÉ DE NANTES

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FACULTÉ DE MÉDECINE

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Année : 2021 N°

THÈSE

pour le

DIPLÔME D'ÉTAT DE DOCTEUR EN MÉDECINE

D.E.S DE CHIRURGIE ORTHOPEDIQUE ET TRAUMATOLOGIQUE

par

Guillaume TRAN

Né le 12 juillet 1992 à Paris

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Présentée et soutenue publiquement le 18 novembre 2021

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Les prothèses massives de fémur en contexte non-oncologique et oncologique. Étude rétrospective sur 189 implants de 2005 à 2020 au CHU de Nantes.

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Président : Monsieur le Professeur Christophe NICH

Directeur de thèse : Monsieur le Docteur Vincent CRENN

« Choisissez un travail que vous aimez,
et vous n'aurez pas à travailler un seul jour de votre vie »

Confucius.

Serment d'Hippocrate

Au moment d'être admis à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré et méprisé si j'y manque

Remerciements

Aux membres du jury

A Monsieur le Professeur Christophe NICH, pour m'avoir fait l'honneur de présider le jury de ma thèse. Exposer ce travail au-devant vos connaissances en chirurgie orthopédique est un honneur. Soyez assuré de ma plus profonde considération et de mon plus profond respect.

A Monsieur le Docteur CRENN, pour m'avoir fait l'honneur de diriger cette thèse. Je te remercie pour l'accompagnement de tous les instants malgré toutes les sollicitations que tu as. Je te remercie également pour ta bienveillance et ta patience à toute épreuve. Sois assuré de ma plus profonde gratitude et de mon plus profond respect.

A Monsieur le Professeur ROSSET, pour avoir accepté de faire partie de mon jury de thèse. Vous avoir écouté lors de ces journées à la SOO n'a fait qu'agrandir le respect déjà immense à votre égard. Votre expertise ne fera qu'ajouter de la valeur à ce travail. Soyez assuré de mon plus profond respect.

A Monsieur le Professeur ROPARS, pour avoir accepté de faire partie de mon jury de thèse. Je suis honoré de bénéficier de votre expertise en matière d'oncologie orthopédique pour juger ma thèse. Soyez assuré de ma plus profonde reconnaissance.

A Monsieur le Professeur GOUIN, pour avoir accepté l'invitation à mon jury de thèse. Avoir eu la chance de travailler dans votre service fut un privilège. Sans votre détermination et votre recherche de l'excellence, ce travail n'aurait pas pu voir le jour. Votre aisance technique et vos connaissances sont des modèles pour tout interne de chirurgie. Soyez assuré de mon respect le plus sincère.

A Monsieur le Docteur Denis WAAST, de me faire l'honneur de juger mon travail. Votre calme en toutes circonstances et votre humilité engendrent la plus grande admiration. Travailler avec vous pendant ces six derniers mois a été une source d'inspiration. Recevez tout mon respect pour tout ce que vous réalisez pour le service.

A mes chefs du CHU de Nantes

Au Dr. TOUCHAIS, et ses connaissances dépassant le cadre de l'orthopédie. Je vous souhaite une belle et joyeuse retraite.

Au Dr. PIETU, pour ses connaissances encyclopédiques et ses conseils toujours précieux. Merci de nous accompagner depuis le départ. Sois assuré de mon plus profond respect.

Au Dr. CAPPELLI, merci d'avoir accompagné pendant six mois. Tes enseignements, ta rigueur chirurgicale exemplaire et ta bienveillance, m'ont fait comprendre la complexité du métier de chirurgien.

Au Dr. GADBLED, ressource d'innombrables connaissances que j'ai eu la chance de côtoyer tôt dans mon cursus. Ton implication et tes ressources chirurgicales ne finiront jamais de m'impressionner.

Au Dr. BRULEFERT, pour sa bienveillance, son talent chirurgical et sa passion partagée pour les sports que personne ne regarde. Merci de ta patience.

Au Dr. QUINETTE, pour ta disponibilité, ta bienveillance et ton humour. Ton soutien durant ces dernières semaines a été précieux. Merci.

Au Dr. RENAULT, pour ta grande bienveillance et ton humour en toutes circonstances. Je ne te souhaite que de la réussite et du bonheur avec ton petit Raph.

A mes anciens co-internes devenus chefs

Au Dr. VARENNE, m'exprimer n'est pas mon fort et tu le sais. Travailler avec toi plus d'une année fut un privilège. Je te remercie pour tout ce que tu as pu me transmettre avec patience et bienveillance. Je te souhaite de vivre avec le plus grand bonheur cette nouvelle vie avec Alice et Juliette.

Au Dr. CARLIER, pour ton humour en toutes circonstances et en plusieurs langues. Ton talent, ta persévérance et ton parcours font de toi un exemple de réussite.

Au Dr. CHAPAT, comment parler de l'un sans parler de l'autre. Ton humour, ta rigueur et tes talents de chanteur n'ont fait que rendre les moments passés à l'hôpital plus agréables.

Au Dr. LATASTE, pour ton investissement de tous les instants et ta grande rigueur qui ont permis de me faire grandir.

Au Dr. MALLET, partager sept mois avec toi a été un réel plaisir. Ta gentillesse, ton appétence pour les jeux de sociétés et le sport ont fait défiler ce semestre trop rapidement.

Au Dr. POUEDRAS, qui malgré toutes les sollicitations a su tout organiser pour nous mettre dans les meilleures dispositions avec décontraction. Merci pour ta bienveillance et ta force de caractère.

Au Dr. LAMBERT, ou lombaire pour les intimes, merci pour les fou-rires partagés dans ce bureau de pédiatrie. Merci pour ta disponibilité et tes conseils toujours bien sentis. Je te souhaite un très bon début de clinicat.

A mes collègues et amis de promotion

Au Dr. EL KINANI Monia, elle qui n'est ni docteur, mais qui l'est maintenant devenue par la force des choses et par son intelligence. Je te remercie pour ta douceur et ta bienveillance.

Au Dr. Alexis COMBAL, dit Bonnisseur de La Bath, ton appétence pour la belle citation, ton humour insatiable lors de ces années passés ensemble ainsi que ton soutien ces dernières semaines ont été des alliés inestimables. J'espère vous rejoindre assez vite.

Au Dr. MOUSSADIKINE Ismaël, merci pour ton humour irrésistible, ta personnalité, ta gentillesse contagieuse. Tu nous permets de rendre plus agréables des moments parfois difficiles. Tu sais ce que je te souhaite pour toi et Lucie mon frérot.

A mes anciens et futurs co-internes

Au Dr. REGENNASS, lulu ou Lucien, merci pour ton humour et ta personnalité. Rien ne te fait peur. Je te souhaite un excellent séjour à Lyon et des rides en moto épiques.

A My-Van pour tes talents de cuisinière et ton espièglerie. J'espère que tu as bien profité de ce séjour pour nous ramener des spécialités du Nord.

A cette promotion dorée, Jean, merci à toi pour ta disponibilité et pour nous tant avoir aidé durant ces derniers mois avec humour. Henri pour ces moments de fou-rires lors des gardes. Jimmy pour ton sérieux et ta sensibilité. Je vous souhaite la plus grande réussite à tous les trois.

A Corentin pour nous avoir fait comprendre que Inesta n'était pas unique, à Julien Behr pour sa gentillesse cachée sous cette grosse carapace, à Émilie pour son implication et son tempérament et Marie L'impératrice pour sa sincérité naïve.

A tous ceux qui sont passés dans le service et qui ont laissé leur traces, Louis-Marie, Anoujat, François (oui), Jérôme, Andy, Émeline, Quentin et Jean.

Aux équipes rencontrées lors de mon internat

A l'équipe médicale et paramédicale du CH de Saint Nazaire, pour m'avoir accueilli avec beaucoup de bienveillance. Merci au Dr. SOUBIGOU, Dr. BIGOTTE, Dr. HEMERY, Dr. JAMARD, Dr. GIRARD, et Dr. SIMON. Travailler dans l'ambiance agréable et familiale de ce centre fut une belle expérience.

A l'équipe médicale et paramédicale du CH de La Roche-sur-Yon, notamment aux Dr. TESSON, Dr. VENET, Dr. LECOUR-GRANDMAISON, Dr. GIRARD, Dr. FRAQUET, Dr. HANNEBIQUE, Dr. COUSIN, Dr. TOANEN. Travailler dans une telle structure a été un honneur pour moi. Je garde votre bienveillance, votre efficacité, vos conseils toujours auprès de moi.

A mes chefs partis vers d'autres aventures, Dr. PERSIGANT, Dr. MESSEDI, Dr. LETEVE, Dr. LONGIS. Vous revoir sera toujours un plaisir.

A l'équipe de chirurgie pédiatrique du CHU de Nantes, qui m'a permis de m'initier à chirurgie infantile.
A l'équipe de Neurotraumatologie du CHU de Nantes qui m'a accueilli pour mon premier semestre à Nantes.

A toute les équipes avec qui nous travaillons tous les jours au CHU de Nantes, anesthésistes, infirmiers anesthésistes, de bloc opératoire, de services, aides-soignants. Sans vous, rien ne tournerait. Merci pour ces quatre années.

A mes amis,

Aux autoproclamés Clara's, que le temps a fini par séparer géographiquement. Heureusement que les souvenirs impérissables de ces années passées ensemble nous poussent à nous voir encore bi-annuellement. Je ne serais pas actuellement ici sans vous, vos soutiens, votre gentillesse et votre bonne humeur contagieuse. Merci à Raph, Flora, Guillaume Tess, Marie, Coline, Faustine, Pauline, Mwetty, Antoine, Ingrid et Gonzague, Gabriel, Fannouche, Antoine, Aurore, Flaubert, Adrien, Isis, Jad, Manon, Yoann, et à toutes les nouvelles belles personnes que vous nous avez fait découvrir, Vincent, Thibault, Robin, Pierre, Adrien. Je suis simplement heureux de faire partie de cette grande famille.

A mes amis du lycée, presque quinze ans pour certains, notre relation pourrait elle aussi rentrer en Seconde... Merci à Keyvan pour ton soutien dans ces derniers mois malgré la distance et pour ces quinze années partagées. Merci à Noé pour ton humour, tes conseils et ta bienveillance. Merci à Manon pour ta douceur. Merci à Solène, Elsa et Clémence pour votre gentillesse et votre humour. Merci à Sébastien pour tous les petits conseils vélo ;). Merci à Pierre-Édouard de me pousser à pratiquer du sport depuis Bruxelles ! Votre présence à mes côtés depuis quinze ans est inestimable. Merci.

A toute la team de l'internat, Charlotte, Lucie, Claire, Clémence, Cécilia, Aliénor, Alexis B, Antoine, Augustin, Adrien, Jeremy, Hassan, Emma, Lise, P.A, Cyprien qui m'ont permis de sortir la tête de l'eau lors de ces premiers mois difficiles !

A ma famille

A mon père et à ma mère, sans qui rien n'aurait été possible, votre combativité et votre persévérance sont des exemples. Merci de votre soutien et vos encouragements.
A Nathalie, ma petite sœur, qui depuis bien trop longtemps me soutient et m'aide, merci pour ton espièglerie qui me fera toujours rire. A très vite pour des débats sans fin que tu ne gagneras pas ;)

Remerciements particuliers : A Madame Morgane PERE, sans qui ce travail n'aurait pas pu aboutir, et Mesdames Juliane BERCHOUD et Peggy AGENEAU, pour leur aide durant toute la durée du projet.

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List of abbreviations

DF : Distal femur.

HAP : Hydroxy-apatite.

HR : Hazard Ratio.

MP : Megaprosthesis.

MSTS : Musculo-skeletal Tumour Society.

NOI : Non-oncological indications.

OI : Oncological indications.

PF : Proximal femur.

THA : Total hip arthroplasty.

TKA : Total knee arthroplasty.

Sd : Standard deviation.

Do femur megaprosthesis revision risk and functional scores differ between non-oncological and oncological conditions?

A monocentric retrospective cohort study of 189 implants

Abstract

Background: Megaprostheses (MPs) are used to manage large bone defects in both non-oncological and oncological conditions. There have been numerous reports on implant-related outcomes such as revision-free survival without distinguishing non-oncological versus oncological causes of implantation, thus leading to undifferentiated results for two heterogeneous populations. Little is known about revision risk and functional score comparison between these groups based on appropriate statistical analysis for femur megaprostheses.

Questions: (i) Do the cumulative incidences of revision of femur MPs differ between non-oncological indications (NOI) and oncological indications (OI)? (ii). Do the cumulative incidences of revision for NOI and OI differ for different anatomical sites (proximal *vs*. distal femur MP)? (iii). Do the complication rates and cumulative incidences of complications differ between NOI and OI? (iv). Do the functional results differ between NOI and OI?

Methods: Between January 2005 and December 2020, a total of 189 implants and 176 patients were included in this retrospective monocentric cohort study (NOI, n=70; OI, n=119) involving METS modular system implants (Stryker, USA (previously Stanmore Implants Worldwide, UK)) during the entire inclusion period. They were 109 (57.6%) proximal femur (NOI, n=52; OI, n=67) and 80 (42.3%) distal femur implants (NOI, n=28; OI, n=42), and all of the implants

were cemented. The mean follow-up for the entire cohort was 47.9 ± 42.6 months. Revision was defined as any reoperation that included skin incision. Complications were assessed following the Henderson classification and the MSTS score was used to determine the functional score. Linear mixed regression was used to compare repeated MSTS measurements between the NOI and OI groups. Competing risk analysis based on the Fine and Gray model was used to estimate the cumulative incidence of revision and complication with death as a competing event and to compare the NOI and OI groups.

Results: (i) The cumulative incidences of revision for all femur MPs were 23.2% and 37.9% for NOI and 30.2% and 35.5% for OI at five and ten years, respectively, without a significant difference (HR=0.81, 95% CI (0.45 – 1.46), p=0.485). (ii) There was no difference in the cumulative incidence of revision between the NOI and OI groups for either anatomical site. The proximal femur cumulative incidences of revision for NOI versus OI were 25.5% and 33.5% versus 29.2% and 32.7% at five and ten years, respectively. For distal femurs, NOI appears to have a better cumulative incidence of revision at five years compared to OI, with 19.3% vs. 31.4% rates, and 39.5% vs. 38.5% at ten years respectively. (iii) NOI appears to be more prone to complications, although there was not a significant difference (HR=1.27, 95% CI (0.78 - 2.06), p=0.332). (iv) Regarding functional results, the MSTS score was significantly better at ten years in the OI (83.1% ± 5.4) group than the NOI group (57.1% ± 22.8) (p=0.011). Subgroup observations showed that, in a non-oncological setting, distal femurs appeared to perform better than proximal femurs at five years (81.1% ±16.0 *vs*. 54.1% ±16.7 respectively).

Conclusion: Our study yielded similar results in terms of the cumulative incidence of revision for NOI and OI in femur MPs, and, despite a non-significant difference, it would appear that NOI were more subject to complications. Nonetheless, in non-oncological settings, it would

appear that distal femur replacement performs better in terms of revision and complications compared to proximal femur replacement. Regarding functional results, the overall MSTS scores were lower in the NOI group, especially for proximal femur prostheses. The aforementioned results call for further prospective investigation with more statistical power. In conclusion, femur MPs can be used in non-oncological settings with a similar revision risk as oncological indications carried out by trained surgeon specialists in a musculoskeletal tumour referral centre.

Keywords: megaprosthesis, revision arthroplasty, competing risk

Level of evidence: IV (retrospective study)

1. Introduction

1.1 Background

Megaprosthesis (MP) has become commonplace in the management of large bone defects. MPs were initially used after primary bone tumour resection, with good implant survival and limb preservation results (1–3). Such favourable results led to extension of the use of MPs for patients with metastatic bone disease with increased life expectancies (4).

Demographic changes in society and increasing numbers of primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) surgeries (5–7) have also made proximal and distal femur MPs an alternative treatment in iterative arthroplasty revision or complex periprosthetic fractures (8–12). They permit broad adaptivity thanks to their modular design, they help manage extended bone loss with structural segment replacement and may provide immediate mechanical stability, thereby allowing early weightbearing and functional recovery. The latter is critical for non-oncological patients, whose initial need is mainly often functional.(13)

In our institution, which is a referral musculoskeletal tumour centre, proximal and distal femurs are the most implanted MPs due, on the one hand, to the frequent femoral localisation of primary or metastatic bone tumours and, on the other hand, due to their increasing use for THA or TKA complex revisions.

1.2 Rationale

For orthopaedic surgeons, who strive to heal these conditions, MPs appear to allow rapid resumption of acceptable function in complex non-oncological situations. However, such results entail a risk of complications that must be taken into account in the surgical decision-making and when informing the patient. While the MP risk of revision and functional scores have been clearly defined in the literature for oncological situations (14–17), it remains less clear for non-oncological surgeries. There have been some studies of MPs without a distinction regarding the oncological status. This may bias results due to strong cofounding factors between

these two populations. Indeed, implantations in this specific condition are still rare and there has been scant comparison between these two groups (18,19). In this context, we decided to study the main critical points: such as revision, complications, and functional outcomes for femur MPs in non-oncological and oncological settings.

Our study sought to answer the following questions:

(i). Do the cumulative incidences of revision of femur MPs differ between non-oncological indications (NOI) and oncological indications (OI)?

(ii). Do the cumulative incidences of revision for NOI and OI differ for different anatomical sites (proximal vs. distal femur MPs)?

(iii). Do the complication rate and the cumulative incidence of complications differ between NOI and OI?

(iv). Do the functional results differ between NOI and OI?

2. Patients and Methods

2.1 Study design

We retrospectively screened patients from medical records using a keywords search on a centralized computer-based platform available in our institution (eHop – CHU Nantes) and from the sales code registry of our institution. Patients who underwent a surgical procedure involving reconstruction of the femur by METS (Stryker, USA (previously Stanmore Implants Worldwide, UK)) between January 2005 and December 2020 were screened.

The inclusion criteria were: (i) patient more than 15 years of age, (ii) proximal femoral replacement or distal femoral replacement; (iii) use of METS implant (Stryker, USA (previously Stanmore Implants Worldwide, UK)); and (iv) minimum follow-up of 6 months. Were excluded all patients under 15 years of age, patients with a custom-made MP, and cases involving a total femur replacement or other than a METS implant.

2.2 Patients

A total of 176 patients and 189 implants were included in our study. The mean follow-up time was 47.9 ± 42.6 months, with NOI=48.3 ± 37.8, and OI=47.7 ± 45.3, with a maximal follow-up of 160 months. Over the course of the study, 53 (28.0%) patients died (NOI=12 (17.1%); OI=41 (34.5)) (**Table 1**). The mean age at surgery was 57.2 ± 21.5 years (NOI=67.3 ± 17.7; OI=51.2 ± 21.4). One hundred and nine (57.7%) proximal femoral replacements and 80 (42.3%) distal femoral replacements were included.

The NOI (n=70) and OI (n=119) groups were divided into subgroups, for the oncological indications (IO), these two groups were: Primary musculoskeletal tumour (n=85) and Metastases (n=34). For the non-oncological indication (NOI), the subgroups were: Revision arthroplasty (n=62), including periprosthetic fractures, revision for periprosthetic joint infection

(PJI), revision for aseptic loosening, and fractures on native bone (n=8). The causes for implantation are summarized in **Fig. 1**.

2.3 Description of the surgery, aftercare, and follow-up

All modular prostheses were METS MPs (Stryker, USA (previously Stanmore Implants Worldwide, UK)). The design of the prostheses did not change over the course of the inclusion period (2005-2020) and all of the implants were cemented with a hydroxyapatite-coated (HAP) collar. All of the surgical procedures were performed by experienced surgeons in a tertiary musculoskeletal tumour referral centre.

For proximal femur replacements, a posterior-lateral approach was used. The approach was at the surgeon's discretion when the surgery involved pelvic resection and reconstruction (n=14, 11.8%). Trochanteric reattachment with a plate was performed in 64 cases (58.7% of proximal femurs), in a digastric way with preservation of the gluteus medius and vastus lateralis continuity whenever possible (20). Screws, K-wire, or surgical thread were used when trochanteric reinsertion with a plate was not feasible. The items used on the acetabular side was left to the surgeon to decide (cup, reinforcement, single mobility (n=7, 6.4%), dual mobility (n=100, 91.7%), constrained liner (n=1, 0.9%), or bipolar head (n=1, 0.9%)).

The approach for a distal femoral replacement was determined by the tumour localisation, biopsies paths, ancient arthrotomy, and therefore at the surgeon's discretion. The surgeons had the choice between three types of hinges (non-rotatory (n=35, 43.7%) – rotatory metal cage (n=21, 26.3%), or full polyethylene cage (n=24, 30.0%).

All of the patients, except PJI's, received preventive antibiotics with first-generation cephalosporin (Cefazolin) excepted in an allergy context. The perioperative data were collected as the operative duration (NOI: 178 ± 54.9 min; OI: 229 ± 127min), blood loss was estimated using Nadler's equation and Mercuriali's formula (NOI: 917.8 ± 1003.2 mL; OI: 822 ± 1370.9)

(21). Post-operatively, the choice of a pelvic brace or knee cast was left to the surgeon to decide depending on the prosthesis stability and the patient's general state for proximal femurs and depending on extensor mechanism resection and reconstruction for distal femurs.

Patients were followed-up clinically and radiographically at regular consultations at six weeks, three months, six months, one year, and then every year until the fifth year after the surgery and then every two years thereafter.

2.4 Outcome measures

Revision was defined as any reoperation with skin incision of the implant, thus excluding closed reduction of dislocation.

Complications related to the implant were assessed using Henderson's classification of failure (22). Type I failure (soft-tissue failure) included instability, tendon rupture, or aseptic wound dehiscence. Type II failure (aseptic loosening) occurred when the patient presented compatible radiographic signs and when microbiology sampling by joint needle aspiration or perioperatively was negative. Type III (structural failure) was determined radiographically for patients with implant breakage or periprosthetic fracture. Type IV (periprosthetic infection) occurred in case of clinically obvious signs of periprosthetic joint infection or with biological sampling. Type V (tumour progression) involved recurrence of the tumour or progression with contamination of the prosthesis.

We used MSTS scores collected from follow-up consultations at six months, one year, five years, and ten years (23) to assess the functional outcomes for OI and NOI patients, and these are presented as percentages. This score has been used systematically since 2017 in our institution. Before this time, the MSTS score was assessed retrospectively based on medical records. Patients who did not have a follow-up consultation were contacted by phone to retrieve the MSTS score.

2.5 Statistical analysis

All of the statistical analyses were carried out using SAS Software (version 9,4, SAS Institute, USA) and R software. The continuous variables are presented as means and the standard deviation (Sd) and compared between OI and NOI groups with Student T test or Mann-Withney-Wilcoxon test if needed. Categorical data are presented as exact numbers and percentages and compared between the two groups with Chi square test or Fisher exact test if needed. Longitudinal continuous data were analysed with linear mixed models with random effects models to consider the repeated measurements within patients.

Revision and complication outcomes were assessed using a competitive risk analysis, with death as a competitive event, and using the Fine and Gray model to compare the NOI and OI groups (24). The assumptions of risk proportionality and log-linearity hypothesis were checked before applying Fine and Gray model. We compared the NOI and OI groups for all types of failure and the NOI to OI excluding type V for failure, as these specific oncological failures were not represented in the NOI group. A p-value < 0.05 was considered significant.

2.6 Ethics

This study started after approval from the local review board of our institution (n°RC210009) and ethics review in accordance with Jardet's law and European conventions. The patients were informed of the study by an announcement on our institution's website (www.chu-nantes.fr). No written consent was necessary due to the study's retrospective design and the use of anonymized data.

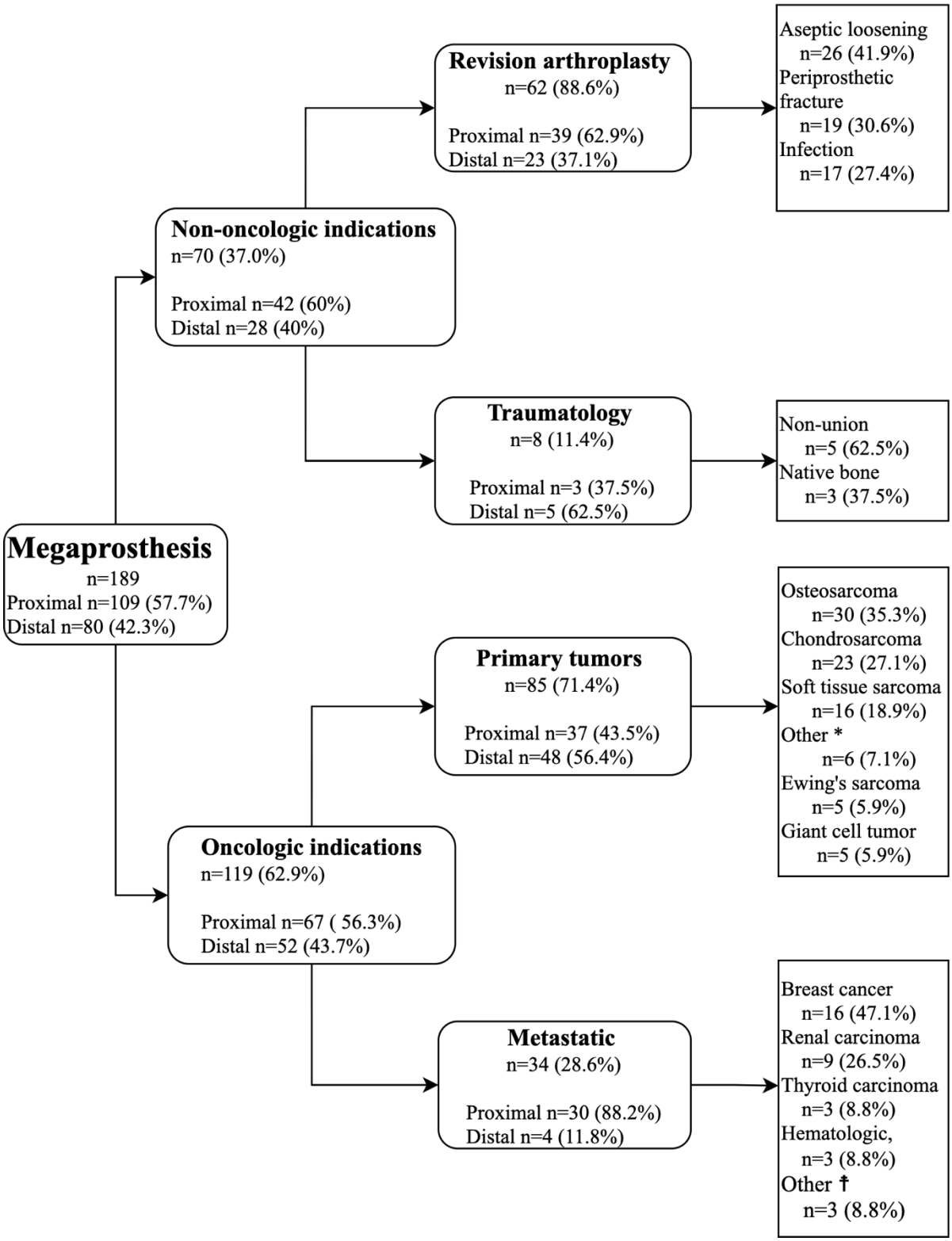

Fig. 1. Cohort distribution in the non-oncological and oncological indication groups.
**: one exostosis, one malignant epithelioid tumour, one osteochondroma, one pilomatrixoma, one FGF-23-producing tumour;* †: *one gastrointestinal stromal tumour, one prostatic carcinoma, and one pulmonary carcinoma.*

Table 1: Demographic, surgical, and oncological data description for the whole population and within the non-oncological and oncological groups.

	Total (n=189)	**NOI** (n=70)	**OI** (n=119)	**p-value**
Demographics				
Age at surgery (years) ± Sd	57.2±21.5	67.3±17.77	51.2±21.4	**< 0.001**
Sex, n (%)				**0.035**
Male	84 (44.4) /105 (55.6)	24 (34.3) /46 (65.7)	60 (50.4) /59 (49.6)	
BMI (cm/kg2) ± Sd	25.1±5.8	24.5±5.8	26.0±5.7	**0.026**
ASA Score, n (%)				**0.029**
1	39 (21.0)	7 (10.3)	32 (27.1)	
2	110 (59.1)	47 (69.1)	63 (53.4)	
3	30 (16.1)	10 (14.7)	20 (17.0)	
4	7 (3.8)	4 (5.9)	3 (2.5)	
Side, n (%)				0.696
Right / Left	91 (48.2) /98 (51.8)	35 (50.0) / 35 (50.0)	56 (47.1) / 63 (52.9)	
Follow up, months ± Sd	47.9±42.6	48.3±37.8	47.7±45.3	0.883
Death, n (%)	53 (28.0)	12 (17.1)	41 (34.5)	**0.011**
Surgical datas				
Anatomical site, n (%)				0.619
Proximal femur	109 (57.7)	42 (60.0)	67 (56.3)	
Distal femur	80 (42.3)	28 (40.0)	52 (43.7)	
Dual mobility cup, n (%)	100 (91.7)	37 (88.1)	63 (94.0)	0.302
Trochanteric plate, n (%)	64 (58.7)	16 (38.1)	48 (71.6)	**<0.001**
Hinges, n (%)				0.157
Fixed	35 (43.7)	11 (39.3)	24 (46.2)	
Rotatory polyethylene	24 (30.0)	4 (14.2)	20 (38.5)	
Rotarory metal	21 (26.3)	13 (46.4)	19 (36.5)	
Resection length (mm) ± Sd	146.3±51.3	141.3± 54.6	148.9±49.5	0.561
Intervention, (min) ± Sd	210.7±109.3	178.3±54.90	229.3±127.3	**0.016**
Blood loss (mL) ± Sd	857.7±1245.5	917.8±1003.2	822.2±1370.9	0.933
Oncological data				
Neoadjuvant therapy, n (%)				**-**
radiotherapy	8 (4.3%)	-	8 (5.0%)	
chemotherapy	50 (26%)	-	50 (42.0%)	-
Adjuvant therapy, n (%)				
adjuvant radiotherapy	25 (13.2%)	-	25 (21.0%)	**-**
adjuvant chemotherapy	52 (27.1%)	-	52 (43.7%)	-

Sd: Standard deviation, NOI: Non-oncological indication, OI: Oncological indication, BMI: Body mass index, p-values for Fischer's exact test for the categorical data, t-test for the continuous variables.

3. Results

3.1 Do the cumulative incidences of revision of femur MPs differ between non-oncological indications (NOI) and oncological indications (OI)?

The cumulative incidence of revision for NOI was 23.2% (95% CI (12.7% - 35.4%)) at five years and 37.1% (95% CI (19.7% - 54.6%)) at ten years. The cumulative incidence of revision for OI was 30.2% (95% CI (21.1% - 39.8%)) at five years and 35.5% (95% CI (25.2% - 45.9%)) at ten years (**Fig. 2, Table 2**). At last follow-up, the cumulative incidence of revision for NOI was 37.1% (12.5 years) and 35.5% at 15 years for OI.

These comprised a total of four amputations (NOI: 1, 1.4%; OI: 3, 2.5%), achieving an overall limb-salvage rate of 97.8%. The overall cohort cumulative incidence of revision was 30.3% at five years, 37.9% at ten years and 37.9% at 15 years (**Table 1**, **Supp. Fig. 1**).

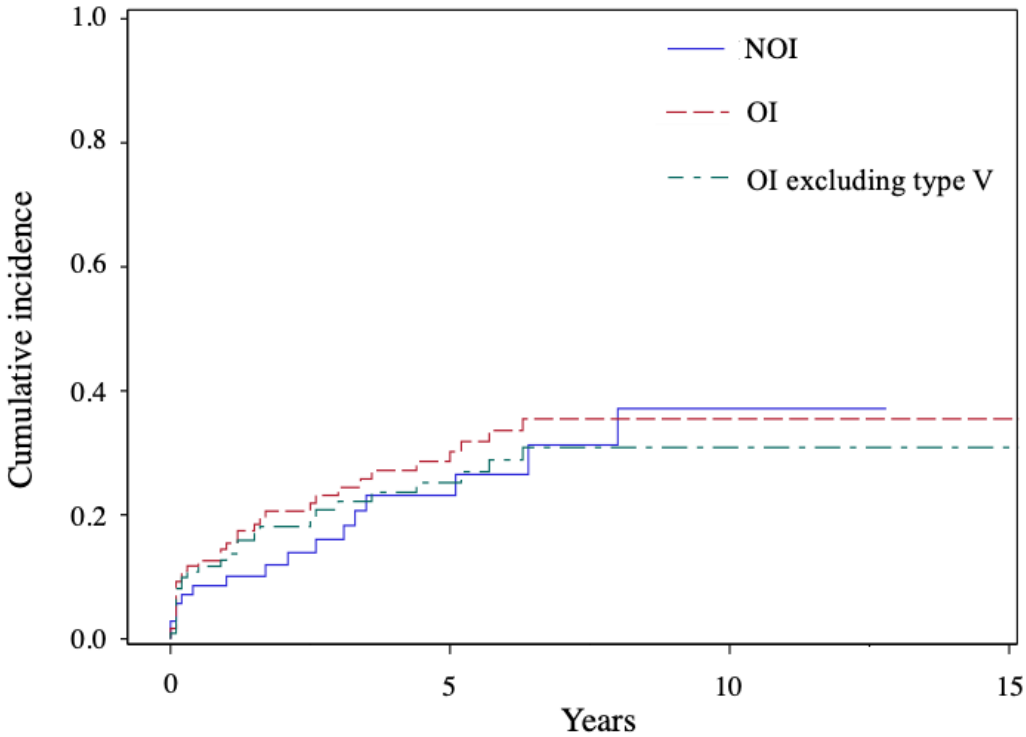

Fig. 2. Plot of the cumulative incidence of revision in non-oncological indications (NOI), oncological indications (OI), and oncological indications excluding Henderson type V. p=0.485 and p=0.871, respectively, for the Fine and Gray test.

Comparison of the cumulative incidence of revision rate did not reveal a significant difference between the two groups for all causes (Hazard Ratio (HR)=0.81, 95%CI (0.45 - 1.46), p=0.485). OI excluding Henderson type V (tumour progression) had a cumulative incidence of revision rate at five and ten years of 25.2% and 30.9%, respectively. No significant difference with NOI was seen (HR=0.95, 95%CI (0.52 - 1.75), p=0.871) (**Table 2**).

Table 2. The cumulative incidences of revision at one, five, and ten years for the whole cohort and non-oncological indications versus oncological indications and versus oncological indications excluding Henderson type V (tumor recurrence) cause of revision

	1y (%)	**5y (%)**	**10y (%)**	**HR**	**95%CI**	***p-value***
All patients * (n=189)	15.0	30.3	37.9	-	-	-
NOI versus OI (n=189)						
NOI (n=70)	10.1	23.2	37.1	0.81	0.45 - 1.46	0.485
OI-all type of failure (n=119)	15.4	30.2	35.5			
NOI versus OI-excluding type V (n=189)						
NOI (n=70)	10.1	23.2	37.1	0.95	0.52 - 1.75	0.871
OI excluding type V (n=111)	13.7	25.2	30.9			

** Cumulative incidence function in **Supplementary Fig. 1***
NOI: Non-oncological indications, OI: Oncological indications, HR: Hazard Ratio, p-values for the Fine and Gray test.

3.2 Do the cumulative incidences of revision for NOI and OI differ at different anatomical sites?

3.2.1 The proximal femur cumulative incidence of revision for NOI versus OI

Comparison between NOI and OI revealed no significant difference in the cumulative incidence of revision for proximal femurs (**Fig. 3**, **Table 3**), with five-year and ten-year cumulative incidences of revision of 25.5% and 33.5%, respectively, and 29.2% and 32.7% respectively (HR=0.90, 95% CI (0.42 – 1.95), p=0.791).

The PF cumulative incidences of revision of OI excluding Henderson type V (tumour progression) at five and ten years were 27.5% and 31.1%, respectively. Comparison with NOI revealed no significant differences in the cumulative incidence of revision (HR=0.92, 95%CI (0.42 - 2.01), p=0.841) (**Fig.3, Table 3**).

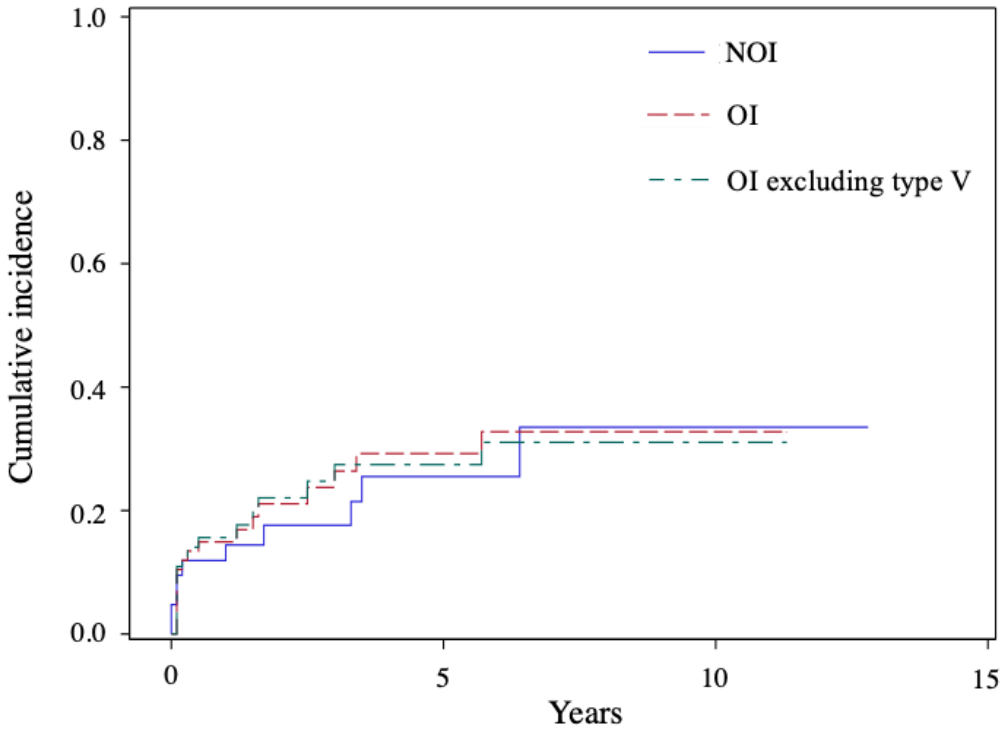

Fig. 3. Plot of the cumulative incidence of revision in non-oncological indications (NOI) and oncological (OI) and oncological indications excluding Henderson type V for proximal femurs. p=0.791 and p=0.841 respectively for the Fine and Gray test.

3.2.2 The distal femur cumulative incidence of revision for NOI versus OI

The cumulative incidences of revision between NOI and OI for DFs at five years were 19.3% and 31.4%, respectively, and 39.8% and 38.5%, respectively, at ten years (**Fig. 4**, **Table 3**). The proportionality hypothesis was not verified for the DF population, and a comparison could not be made. The Fine and Gray test between NOI and OI excluding type V cannot be applied for the same reason.

The cumulative incidences of revision of OI excluding Henderson type V (tumour recurrence) were 22.3% and 30.4% at five and ten years, respectively.

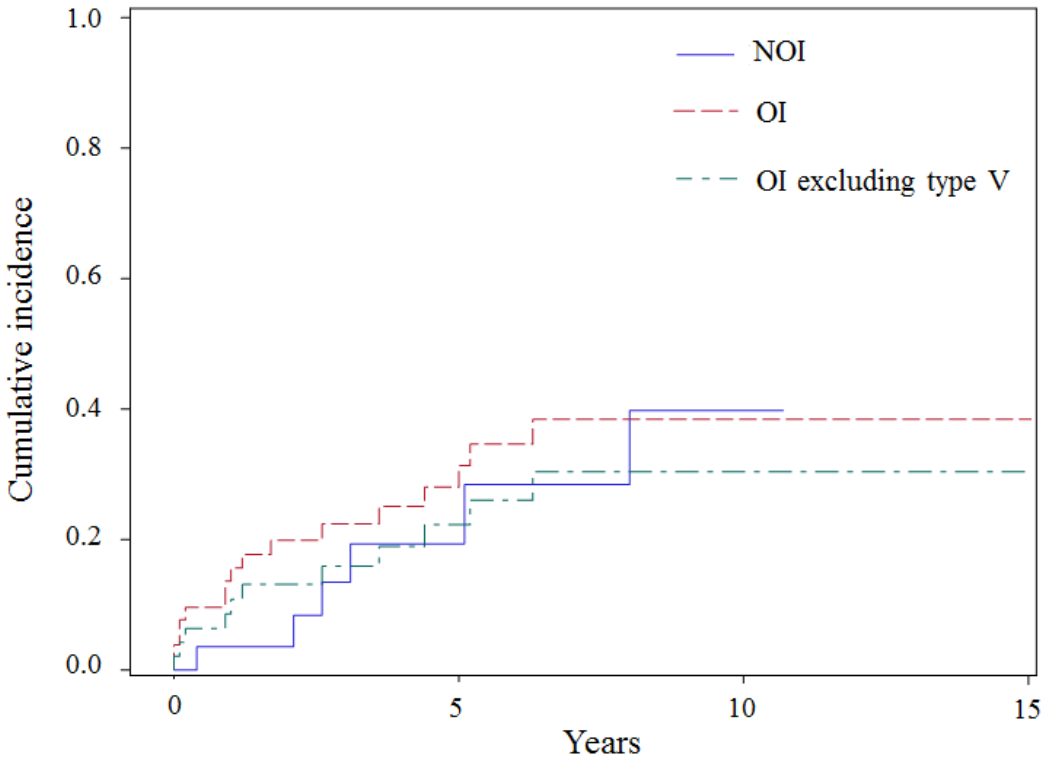

Fig. 4. Plot of the cumulative incidence of revision in non-oncological indications (NOI) and oncological indications (OI) for distal femurs. The proportionality hypothesis was not verified.

Table 3. The cumulative incidence of revision between NOI and OI, in proximal and distal femurs.

	1y (%)	**5y (%)**	**10y (%)**	**HR**	**95%CI**	***p-value***
Anatomical site						
Proximal Femur (n=109)						
NOI (n=42)	14.4	25.5	33.5	0.90	0.42 ; 1.95	0.7914
OI-all type of failure (n=67)	14.9	29.2	32.7			
Proximal Femur (n=109)						
NOI (n=42)	14.4	25.5	33.5	0.92	0.42 ; 2.01	0.8409
OI excluding type V (n=64)	15.6	27.5	31.1			
Distal Femur (n=80)						
NOI (n=28)	3.6	19.3	39.8			
OI-all type of failure (n=52)	15.7	31.4	38.5			
OI excluding type V (n=47)	17.2	22.3	30.4			

OI: Oncological indications, NOI: Non-oncological indications; proportionality hypothesis was not verified for distal femurs, HR: Hazard Ratio, p-values for the Fine and Gray test.

3.3 Do the complication rate and the cumulative incidence of complications differ between NOI and OI?

3.3.1 The overall complication rate

We reported a total 91 (48.1%) complications during the follow-up. The complications related to the implant primarily comprised Type IV (infection, n=30 (15.9%)), followed by Type I (soft-tissue failure, n=22 (11.6%)), Type II (aseptic loosening, n=13 (6.8%)), and Type III (implant failure or periprosthetic fracture, n=9 (4.8%)).

We did not find there were significant differences between NOI and OI in terms of the occurrence of Henderson complications (**Table 4**).

Table 4. The incidence of complications for non-oncological and oncological indication according to Henderson classification with the number that led to a revision

	Total (n=189)	**NOI (n=70)**	**OI (n=119)**	***p-value***
Type I (soft-tissue failure)	22 (11.6%)	7 (10.0%)	15 (12.6%)	0.590
leading to revision	12 (54.5%)	4 (57.1%)	6 (40.0%)	
Type II (Aseptic loosening)	13 (6.9%)	6 (8.6%)	7 (5.9%)	0.556
leading to revision	7 (53.8%)	2 (33.3%)	5 (71.0%)	
Type III (Implant breakage)	9 (4.8%)	2 (2.9%)	7 (5.9%)	0.489
leading to revision	6 (66.7%)	0 (0.0%)	6 (85.0%)	
Type IV (Infections)	30 (15.9%)	13 (18.6%)	17 (14.3%)	0.436
leading to revision	28 (93.3%)	11 (84.6%)	15 (88.2%)	
Type V (Tumor progression)	8 (4.2%)	-	8 (6.7%)	-
leading to revision	5 (62.5%)	-	5 (62.5%)	-

NOI: Non-oncological indication, OI: Oncological indications, p-value for two-sided Fischer's test.

Type V were not represented for the NOI group, while in this series we noted eight (6.7%) incidences of tumour progression in the OI group. Seven (5.9%) of these were for primary tumour indications and one (0.8%) was in the metastatic group, and all but three lead to revision.

For proximal femurs, dislocation occurred nine times in our cohort (8.8%), for six patients (14%) in the NOI group and three patients (4.5%) in the OI group. Four patients had iterative dislocations. One patient (1.0%) in the NOI group needed open reduction.

3.3.2 The cumulative incidence of complications for NOI versus OI

We were unable to find a significant difference in the cumulative incidence of complications between NOI and OI (HR=1.27, 95% CI (0.78 - 2.06), p=0.332) despite cumulative incidence of complication of 42.1% and 60.9% versus 33.6% and 40.3% at five and ten years, respectively. (**Table 5, Supp. Fig. 2**).

Table 5. The cumulative incidences of complications at one, five, and ten years for non-oncological and oncological indications for the whole cohort and for specific anatomical sites

	1y (%)	**5y (%)**	**10y (%)**	**HR**	**95%CI**	***p-value***
NOI *vs.* OI (n=189)						
NOI (n=80)	17.3	42.1	60.9	1.27	0.78 - 2.06	0.332
OI (n=109)	18.9	33.6	40.3			
Anatomical site						
Proximal Femur (n=109)						
NOI (n=42)	23.9	46.0	63.2	1.50	0.80 - 2.80	0.204
OI (n=67)	18.3	34.8	38.2			
Distal Femur (n=80)						
NOI (n=28)	7.1	35.9	57.6	1.00	0.46 - 2.15	0.994
OI (n=52)	19.4	32.6	42.7			

OI: Oncological indications; NOI: Non-oncological indications, HR: Hazard Ratio, p-value for Fine and Gray Test.

Despite differences in the results for proximal femurs between NOI and OI, with cumulative incidences of complications of 63.2% and 38.2%, respectively, at ten years, the result was not significant (HR=1.50, 95%CI (0.80 - 2.80), p=0.204) (**Table 5. Supp Fig. 3**).

The cumulative incidences of complications for distal femurs were not significantly different between NOI and OI, with 57.6% and 42.7%, respectively, at ten years (HR=1.00, 95%CI (0.46 - 2.15), p=0.994) **(Table 5. Supp Fig. 3**).

3.4 Do the functional results differ between NOI and OI?

3.4.1 Comparison of the MSTS score between NOI and OI

The mean MSTS scores for NOI MPs were 64.1% ± 21.4 and 57.1% ± 22.8 at five and ten years, respectively, vs. 73.1% ± 21.4 and 83.1% ± 5.4 at five and ten years, respectively, in OI. The overall cohort MSTS scores were 69.3% ± 21.7 at 5 years and 74.4% ± 21.7 at 10 years (**Table 6**). We did not observe a difference in the mean MSTS until the 10th year of follow-up (p=0.011) using the Mann-Whitney-Wilcoxon test (**Fig. 5**), and linear mixed regression found a significant difference throughout the follow-up between NOI and OI adjusting for repeated measurements, with a decrease of 0.9% per year for NOI compared to OI. (Estimate: -0.9, p=0.026) **(Table 6)**

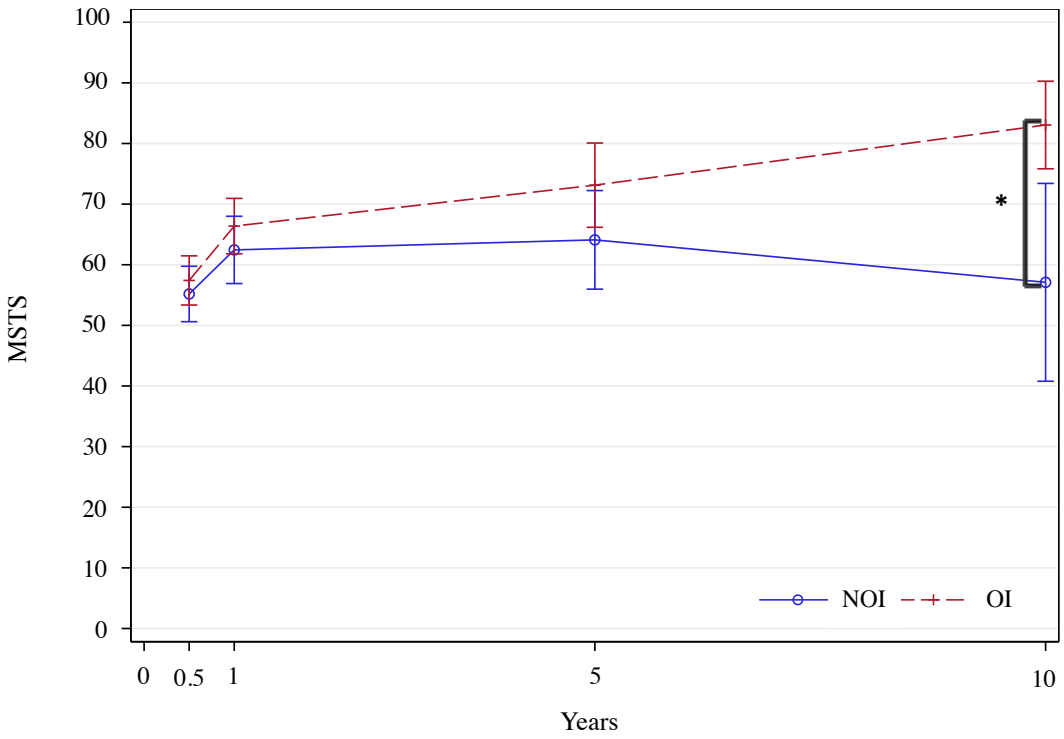

Fig. 5. The mean MSTS percentages distribution throughout the follow-up, with the 95%CI of the mean represented. *: p=0.011 for the Mann-Whitney-Wilcoxon test.

3.4.2 Comparison of the MSTS between NOI and OI in proximal femurs and distal femurs

For the mean MSTS in proximal femurs, we found significant differences with linear mixed regression throughout the follow-up, with 48.3% ± 10.9 for NOI versus 78.2% ± 19.5 for OI at ten years **(Table 6, Supp Fig. 4).** A decreased rate was found for PF NOI, with a mean MSTS decrease of 1.3% per year (estimate: -1.3, p=0.012*)*.

Distal femurs had no significant difference in the functional outcome in linear mixed regression throughout the follow-up (estimate: -0.16; p=0.823) between NOI (83.1% ± 16.0 at five years) and OI (77% ± 20.1 at five years) (**Table 6, Supp. Fig. 4**).

Table 6. The mean MSTS percentage distribution for non-oncological (NOI) and oncological indications (OI) for all patients and in proximal and distal femurs, presented as percentages ± the standard deviation (n= numbers of scores collected)

	6 months	**1 year**	**5 years**	**10 years**	***p-value****
All patients	56.6±20.2 (n=176)	64.8±20.7 (n=137)	69.3±21.7 (n=68)	74.4±21.7 (n=30)	
NOI *vs.* OI					0.026
NOI	55.2±18.6 (n=69)	62.4±20.3 (n=54)	64.1±21.4 (n=29)	57.1±22.8 (n=10)	
OI	57.4±21.2 (n=107)	66.4±20.9 (n=83)	73.1±21.4 (n=39)	83.1±5.4 (n=20)	
Anatomical site					
Proximal Femur	49.7±18.4 (n=103)	58.4±20.0 (n=73)	60.7±20.7 (n=36)	65.1±22.0 (n=16)	0.012
NOI	48.9±16.7 (n=42)	55.8±18.0 (n=31)	54.1±16.7 (n=19)	48.3±10.9 (n=7)	
OI	50.2±19.6 (n=61)	60.3±21.4 (n=42)	68.1±22.7 (n=17)	78.2±19.5 (n=9)	
Distal Femur	66.1±18.8 (n=73)	72.1±19.1 (n=64)	78.9±18.9 (n=32)	85.0±16.3 (n=14)	0.823
NOI	64.5±18.0 (n=27)	71.4±20.2 (n=23)	83.1±16.0 (n=10)	-**	
OI	67.0±19.4 (n=46)	72.6±18.7 (n=41)	77.0±20.1 (n=22)	87.0±10.5 (n=13)	

**p-value for linear mixed regression comparison throughout the follow-up. **Only one patient reached 10 years of follow-up in this group (MSTS = 50%)*

4. Discussion

4.1 Background and rationale

Our study aimed to compare the cumulative incidences of revision, the complications, and the functional outcomes of femoral MP implants in limb salvage situations in non-oncological condition versus oncological indication. The limb salvage rate, the complications, and the functional results of femoral MPs have already been assessed by many authors in oncological conditions, with good overall limb-salvage rates but with a high risk of complications (1,3,8,11,25). Furthermore, although several studies have reported results regarding revision after hip or knee replacement by massive implants without distinguishing oncological versus non-oncological situations, very few have compared the incidences of revision for these two situations (19,26,27).

We might expect MPs to follow the pattern of projected increases of primary or revision hip and knee arthroplasty (5–7), as they are thought to provide simple solutions to complex situations such as iterative THA and TKA revisions associated with extended bone loss. With an aging population, MP implantation should be considered very carefully in these non-oncological settings, and we believe that this study could provide practitioners more concrete reference points for revision, complications, and functional outcomes with oncological settings as a reference point.

In this study, we address this issue by studying data from proximal and distal femur MPs, which are two of the most implanted MPs. These two implants, initially devised for tumour conditions, differ in terms of their anatomic specificities and mobility mechanisms; but they also share interesting similarities, such as their fixation principles, modularity, and bone segment replacement concept. These reasons encouraged us to study them jointly, in order to retrospectively observe any possible differences between NOI and OI in femur MPs. However,

a separate study of PF and DF was carried out to highlight subtle particularities between these two anatomical sites.

From a methodological point of view, on the one hand, we chose to study revision, complications, and function, as these are key elements for the decision-making by using classifications design for oncological purposes but used in non-oncological settings.

On the other hand, death seems to be a critical competing event that could bias the results, as it occurred for 28.0% of the entire patient cohort (NOI: 17.1% *vs*. OI: 34.5%, p=0.011). In order to limit confounding factors and misestimation, we performed a competing risk analysis on this event (28–30), using proportionality tests every time the Fine and Gray model was used (31). This statistical method yields more accurate results, reducing our cohort's heterogeneity and increasing the group comparability. Nevertheless, as it is not yet a widely used method in orthopaedics research, it restricts external comparison, as most studies use the more conventional Kaplan-Meier analysis.

4.2 Limitations and strengths

Our study has several limitations. These comprise (i) during the 15-year inclusion period, both the understanding and the management of complications and therapies for oncological diseases have evolved. (ii) The retrospective design of this study makes it susceptible to selection bias. (iii) Due to the number of patients lost to follow-up, our results are subject to interpretation and generalization. (iv) In this study, implantations were performed by multiple experienced surgeons in an institution specialized in treating musculoskeletal tumours. (v) Our cohort was quite heterogeneous, with various indications. (vi) Due to retrospective design, we were not able to include specific hip or knee functional scores, or a generic quality of life assessment score, and we could not compare pre- and post-operative functional outcomes. (vii) MSTS before 2017 were assessed retrospectively by a single

investigator based on medical records using clinical data. (viii) Finally, despite our large cohort, we could not exclude a lack of statistical power.

Despite these limitations, our work has several strengths, as (i) we studied a single implant brand (METS (Stryker, USA (previously Stanmore Implants Worldwide, UK))), the design of which did not change during the study period, with the same cemented and HAP collar design. (ii) We used a statistical method that suited our heterogeneous decreased rate. (iii) Our sample size is relatively high compared to the literature to date on this subject. (iv) We have a maximum of fifteen years follow-up in this study. (v) We believe that our broad inclusion criteria for this study reflect everyday practice and readily allow for generalization, thus providing clinically useful insights regarding MP revision, complications, and functional scores in NOI situations compared to OI, which in turn can result in better knowledge and practice in regard to this condition.

4.3 Do the cumulative incidences of revision differ between non-oncological and oncological indications?

The cumulative incidences of revision between NOI (23.2% and 37.1% at five and ten years, respectively) and OI (30.2% and 35.5% at five and ten years, respectively) were not significatively different, with an overall cumulative incidence of revision of 30.3% and 37.9% at five and ten years, respectively, in our cohort.

As expected, and while remaining cautious about the statistical methods used by others, the high cumulative incidence of revision in this study appears to be in line with the revision rates already described in oncological situations in literature. For example, for femur MP implants, Capanna et al. (3) noted risks of revision of 24.1% and 34% at 5 and 10 years, respectively, and Jeys et al. (32) a revision risk of up to 42% at ten years. Our aforementioned results for the non-oncological group also seems to be in keeping with the rare results described in the literature,

such as Viste et al. (8), with an estimated five-year risk of revision of 34% for PF replacement in hip-revision arthroplasty, and an estimated 27% risk of revision at five years in DF replacement according to Berend et al. [4].

Bearing in mind that our objective was to compare non-oncological and oncological settings, this study found a slight but non-significant difference in favour of the NOI group (HR=0.81, 95%CI (0.45-1.46), p=0.485). In this regard, we confirmed the results of Staats et al., who did not observe a statistical difference in the revision cumulative incidence between these two groups (19). When we excluded type V causes for revision from the analysis, we noted a more similar overall cumulative incidence of revision between the NOI and OI groups (HR=0.95, 95%CI (0.52-1.75), p=0.871), highlighting a very similar risk of revision in these heterogeneous group.

The causes for the latter may be multiple, and there are setbacks in establishing clear relations, due to the heterogeneous population characteristics making them both vulnerable in different ways in non-oncological and oncological settings.

On the one hand, the NOI patients were indeed older (NOI: 67.3 ± 17.7 versus OI: 51.2 ± 21.4 years, $p < 0.001$) and they had worse ASA scores (p=0.029), reflecting a higher probability of chronic diseases that can lead to revisions and complications. Colman et al. (33) reported a seemingly cumulative incidence of revision (38.0% at five years) using competing risk analysis in a retrospective series with PF for periprosthetic fractures of the hip, and they hypothesized that being relatively old, multi-operated sites, and a higher BMI, among other factors, may explain these values. Indeed, in our institution, the use of MPs in revision arthroplasty or management of complex traumatology is still a salvage solution, meaning that NOI patients have a higher probability of having several surgeries before the implantation (excluding the rare native bone traumatic cases), and these factors render them more susceptible to complications such as infections and soft-tissue failure, which lead to revision. Moreover,

this group of patients with periprosthetic joint infections is at high risk of re-infection, as Jeys et al. found re-infection rates of 27% and 15% after one or two-stage revision, respectively, for infected megaprosthesis of proximal femur (32).

On the other hand, several other factors could explain similar high revision rates in OI and are well describe in literature. The patients were indeed younger (51.2 ± 21.4 years), but most were diagnosed with malignant diseases and had neo-adjuvant or adjuvant treatment during the perioperative period (neo-adjuvant chemotherapy: n=50 (42.0%), adjuvant chemotherapy: n=52 (43.7%), and adjuvant radiotherapy: n=25 (21.0%)). In addition, well-known risk factors such as internal-pelvectomies (n=14, 20.8% of PF in oncological indications) and a lengthy surgical time in the OI group (229.3 ± 127.3 mins) add to these contributing factors favouring revision (34). Our results for the cumulative incidence of revision for OI (30.2% and 35.5% at five and ten years, respectively) are nevertheless higher than what was recently reported by Yilmaz et al. (35) using competing risk analysis on lower limb MPs, with an estimated cumulative incidence of revision of 14% and 25% at five and ten years, respectively, in a large multicentre retrospective cohort study of 119 oncological indications of MP. However, the authors reported a lower rate of infection (9.0%), which could contribute to the better results.

As a matter of fact, there have been few published studies that compared femur MPs in both non-oncological and oncological settings using competing risk analysis. Looking at other series using Kaplan-Meier survival analysis and comparing our results to revision-free, or implant survival is, as stated before, difficult and could lead us to misinterpretation of our findings. As Biau et al. demonstrated for implant survival (28), the Kaplan-Meier analysis overestimates the revision rate over time in the presence of a competing event. As the mortality rates in the NOI and OI groups were significantly different in our study, we remain careful about comparison with other studies using this statistical measure, as the occurrence of death may be a strong confounding factor.

Overall, our results and the literature suggest that the risk of revision appears to be similar despite dissimilar populations, but other confounding factors could have influenced our aforementioned results.

4.4 Do the cumulative incidences of revision for NOI and OI differ for different anatomical sites?

4.4.1 The proximal femur cumulative incidence of revision for NOI and OI

Focusing on the proximal femur cumulative incidence of revision for NOI and OI (22.5% *vs*. 29.2% at five years and 33.5% *vs*. 32.7% at ten years, respectively), they were not significantly different.

These high rates were to be expected in oncological conditions and remained equivalent in NOI conditions in our work concerning PFs. Although we did not apply the same statistical method, they appear to be in line with the literature, with Ahlmann et al (36) reporting a risk of revision of 27% at five years and Pala et al. (17) reporting a risk of revision of up to 43% at 8 years for proximal femur replacement in OI settings involving more than 200 patients. Regarding the NOI group, the results also appear to be in keeping with the literature, with Parvizi et al. (37) reporting an estimated risk of revision of 27% at five years for 48 proximal femur replacements, but lower than a recent report by Doring et al. (25) of 54% and 61.9% risk of revision at five and ten years, respectively, for 28 proximal femur replacements.

The causes for these similarities in results between these two heterogeneous populations are discussed above, and if we consider the cumulative incidence of revision excluding type V (tumour recurrence) of revision for the OI group, they once again appear to be similar (HR=0.92, 95% CI (0.42 - 2.01), p=0.841)). These results suggest that these two populations experienced the same risk of revision despite their demographic differences. Nevertheless, there

is, to our knowledge, no literature that compared these two populations using competing risk analysis for proximal femur replacement.

4.4.2 The distal femur cumulative incidence of revision for NOI and OI

Focusing on distal femur cumulative incidences of revision in DF at one, five, and ten years, the risk was 3.6%, 19.3%, and 39.8%, respectively, for NOI versus 15.7%, 31.4%, and 38.5% for OI, and 17.2%, 22.3, and 30.4% for OI excluding type V of failure.

The non-proportionality of hazards between the groups did not allow proper statistical comparison and could be explained here by the strong difference in the cumulative incidence of revision at one year after surgery (NOI: 3.6% versus OI-all failure mode: 15.7%).

This notable early lower risk of revision at one and five years in the NOI group needs to be mentioned. It could be explained as mentioned before by immune-suppressive treatments and carcinologic surgeries, associated with soft tissue resection in the OI group. Indeed, these patients are at high risk to type I and IV failure, as suggested by Pala et al. (38), who found a difference of 15% in the revision risk at four years in favour of failed tumour reconstruction compared to first implantation MPs in oncological conditions.

Nevertheless, these early cumulative incidences of revision rates appear to become similar in the second part of the follow-up, suggesting that NOI patients experience a different evolution pattern, as described by Vertesich et al. (39), who reported revision due to type II and type III in non-oncological distal femoral replacement mostly in the second part of the follow-up in their study. Our findings, combined with those in the literature, suggest that NOI patients may experience a revision-free period, with a risk of revision that increases in the long term. This result appears to be a non-negligible factor when considering the higher age of the NOI population.

In a similar competing risk analysis of 80 cemented DFs, Staats et al. (19) showed that there was no significant difference between the NOI and OI groups (68.5% versus 35.9%, respectively, at five years for cemented stems) with a clear tendency for the oncological group. Despite our lower cumulative incidence at ten years (NOI: 39.8% versus OI excluding type V complications: 30.4%), and our equivalent sample size for cemented implants, we were unable to apply the Fine and Gray model because of a lack of statistical power. These somewhat disconcerting results call for more investigation.

4.3 Do the complications differ between NOI and OI?

4.3.1 Overall complications

The main complications reported were infections, aseptic loosening, and instability. In this study, we were unable to find a significant difference in the overall complications between NOI and OI. With type IV (infections) (NOI: 18.0%, n=13 *vs*. OI: 14.3%, n=17) being the first cause of failure, this high rate of infections could be affected, as already mentioned, by our cohort selection. Although the type IV failure rate in this study appears high, it is in keeping with the recent literature for non-oncological and oncological indications (25,35,40). Moreover, neither Toepfer et al. (NOI: 9.7% *vs*. OI: 3.7%) and Staats et al. (NOI: 2.6% *vs*. OI: 11.8%) found significant differences in the infection rate for PF and DF in these two indications (19,27).

Overall, type I failure represented 11.6% (n=22) of complications (NOI: 10.0%, n=7 *vs*. OI: 12.6%, n=15) and they were mainly dislocations (4.7%, n=9). However, the patients appeared to experience a different yet non-significant risk of dislocation (NOI: n=6; 14% *vs*. OI: n=3; 4.5%). The cause for this dissimilarity may be found in the dissymmetric use of trochanteric plates (NOI: n=16; 38% *vs*. OI: n=48; 71%), which were used for the abductor system repair in our study, and which could have influenced the dislocation rate. As a matter of fact, several authors claim that a digastric reinsertion of the abductor system preserves its muscular strength,

which is thought to be essential as a positive prosthetic stability factor (20,41). The difference could be attributed to surgical factors such as iterative surgeries inducing weaker gluteus muscles, and also severe bone loss due to aseptic or septic loosening in the non-oncological group.

Thus, our low overall rate of reported dislocations (4.7%, n=9) is mainly due to the extensive use of dual-mobility cups in our institution, and this can be compared to the 27.5% rate of dislocation recently observed by Toepfer et al. with the use of conventional cups (27).

Type II failure represented 6.9% of complications (NOI: 8.6%, n=6 versus OI: 5.9%, n=7), and appears to be in keeping with the recent literature regarding cemented implants, with Staats et al. also reporting no significant difference between NOI and OI in type II failure, while underscoring the benefit of cementation on type II failure in their multivariate analysis (19).

4.2.2 Cumulative incidence of complications

The cumulative incidences of complications for NOI and OI were 42.1% and 33.6% at five years and 60.9% and 40.3% at ten years, respectively. These rates appear to be in keeping with the literature for the cumulative incidence of complications using competing risk analysis (18,42–44). Notably, Smolle et al. (18) were not able to find an association between complication occurrence and oncological status in their study.

Despite a non-significant difference between NOI and OI, there was a higher cumulative risk of complications for the NOI group in this series, with a greater difference for PFs in particular, which were prone to a higher complication risk. This first highlights the fact that patients will experience minor complications that will not necessarily lead to revision surgery. In addition, the higher age of the NOI patients could be one of the factors contributing to this observation. As a matter of fact, as they age, patients are prone to develop diseases that make surgeons and anaesthesiologists more reluctant to perform major surgical procedures, which

historically are thought to involve a high level of morbidity and mortality. This could reflect our past fifteen years habits, although during this period management and aftercare of this specific group of population has changed (45). Khajuria et al. (46) recently also reported evidence for a low incidence of perioperative complications and mortality in this high-risk population, with acceptable short-term risk of revision according to our findings.

4.4 Do functional results differ between NOI and OI?

Functional outcomes were measured with MSTS scores (23). Despite being used for oncological purposes, this score has also been used to describe the functional results of MPs in non-oncological settings (17,26,27). Before being used routinely for oncological patients from 2017 onwards, the MSTS score was assessed based on medical records and could lead us to biased interpretation. Nevertheless, MSTS scores were generated by a single investigator, thus limiting the potential for bias, and a recent report (47) has underscored the reproducibility of MSTS scores based on medical records, with an slight inherent risk of overestimation.

We observed a significant difference in the mean MSTS score percentages, with an 82% score at ten years in OI versus 57% at ten years for NOI. The patients tended to have scores that diverged over time, with increasing scores for the OI patients over time and mostly stable scores for the NOI patients.

One hypothesis for the relatively stable MSTS scores is once again linked to demographic specificities such as higher age and a worse ASA grade for the NOI patients. As they progress through life, they tend to be more dependent and may have decreasing or stable scores. This hypothesis has been verified by Toepfer et al. (48), who compared distal femoral replacement in oncological and non-oncological conditions and highlighted that age was the most influential factor on MSTS scores differences.

From an anatomical site point of view, the previous overall results are mostly influenced by the predominant number of PF patients in our entire cohort. Indeed, interestingly, DF patients tended to have similar results at five years, with mean MSTS scores for NOI of 83.1% ± 16.0 vs. 77.0% ± 20.1 for OI, whereas PF patients appear to have worse results, with mean MSTS scores of 54.1% ± 16.7 for NOI at five years and 68.1%± 22.7 for OI at five years.

One possible explanation for worse results between NOI and OI in the PF group could be the poorer muscle status of the abductor system postoperatively due to multi-operated hips. Toepfer et al. (27) obtained similar results for PFs, with NOI MSTS scores of 61.1% versus 74.8% for OI. Aside from cultural dissimilarities restraining the comparability to our results, the authors align with our hypothesis underlining age, comorbidities, and repeated surgical procedure as possible factors contributing to worse MSTS scores in the NOI group.

Finally, if NOI versus OI are considered without distinguishing the anatomical site, the patients in OI appeared to have better results over time compared to the NOI patients. But our study highlights that in non-oncological settings, patients who have had a distal femoral replacement are less impaired than those with a proximal femoral replacement.

5. Conclusion

This study did not find significant differences for the cumulative incidence of revision and complication between non-oncological and oncological indications, with similar results in the NOI and OI groups. Nevertheless, MPs appear to present a high risk of revision and complication in both populations. When focusing on the anatomical site, distal femur replacement in non-oncological settings appears to result in a lower rate of early revisions compared to OI. Regarding functionality, significant results in favor of the OI group were found, with stable scores over time in NOI, but intra-group observation appears to show that distal femur MPs perform well in NOI conditions compared to PFs. These results suggest that patients eligible for THA and TKA complex revision might benefit from MP implantation and experience acceptable rates of revision and complication associated with satisfactory functional results, especially in distal femur localization.

This study also underlines the need for further larger prospective multi-center studies, as these implantations are still rare in non-oncological conditions. We believe that a prospectively maintained nationwide data register of MPs could provide more statistical power and a better picture of the pre-operative and post-operative factors influencing revision, complication, and functional outcomes in various targeted populations.

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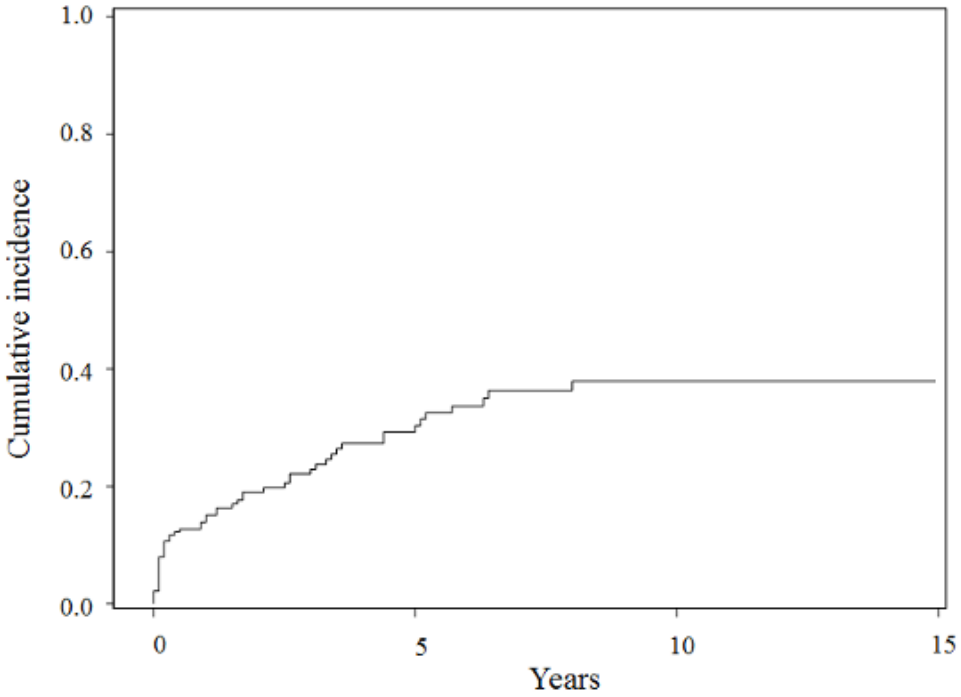
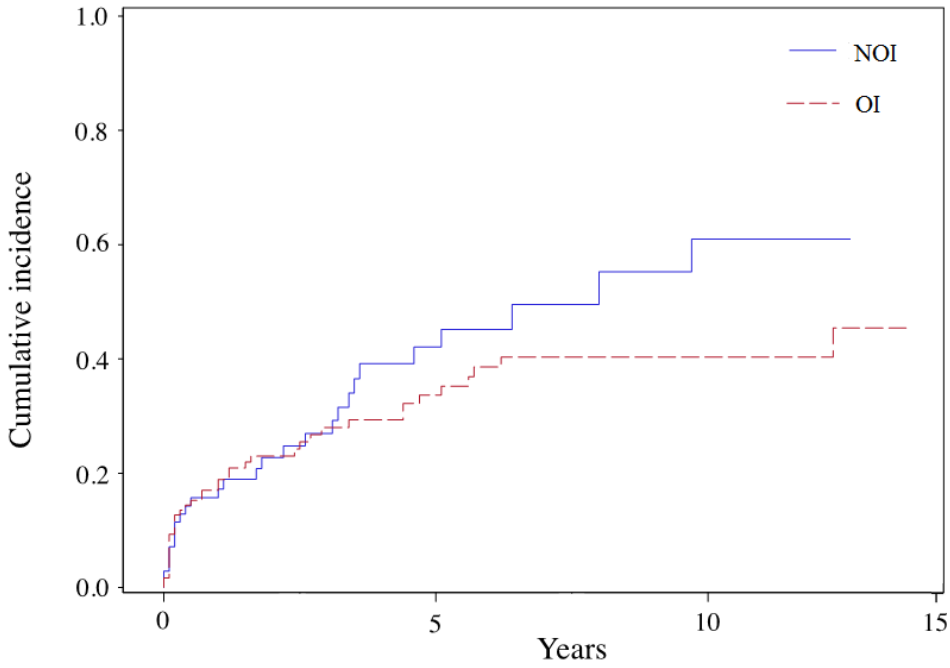
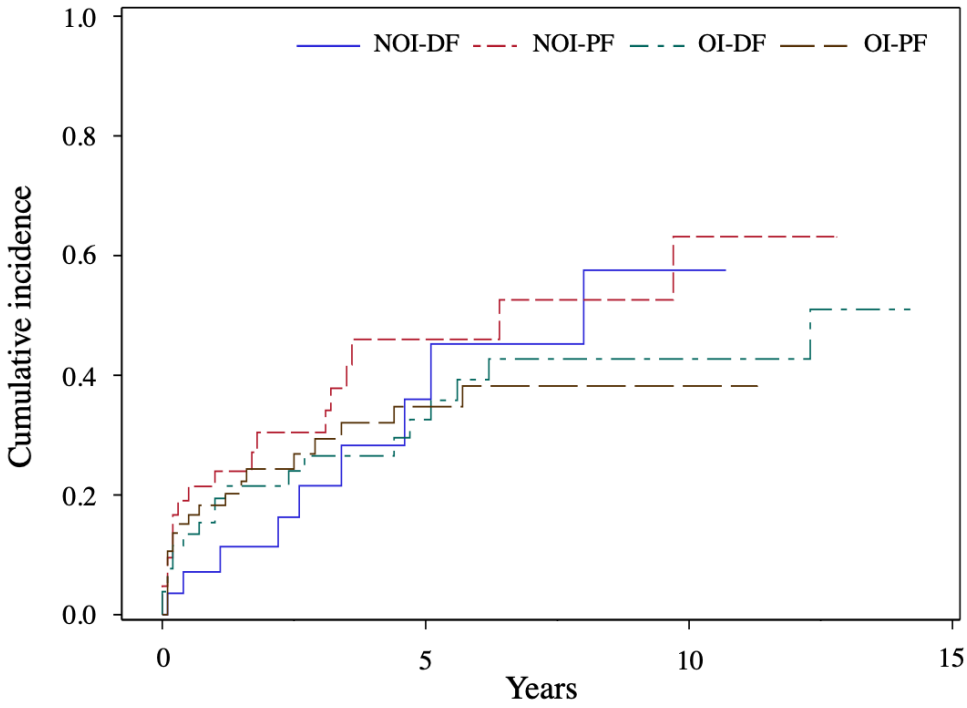
Supplementary data



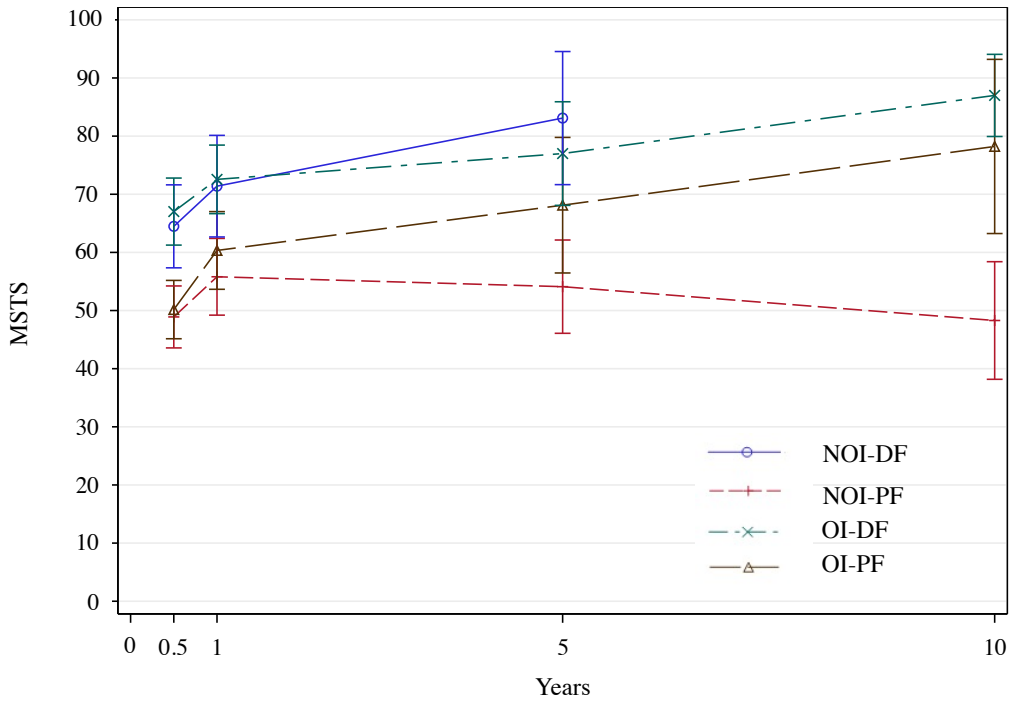
Supplementary Fig. 1. Plot of the overall cumulative incidence of revision in our cohort.



Supplementary Fig. 2. The cumulative incidence of complications for the NOI and OI groups.



Supplementary Fig. 3. Plot of the cumulative incidence of complications for non-oncological proximal femurs, non-oncological distal femurs, oncological proximal femurs, and oncological distal femurs. *NOI-DF: Non-oncological distal femurs, OI-DF: Oncological distal femurs,* p=0.204 for the Fine and Gray test. *NOI-PF: Non-oncological proximal femurs, OI-PF: Oncological proximal femurs,* p=0.994 for the Fine and Gray test.



Supplementary Fig. 4. The mean MSTS score distribution over time for non-oncological proximal femurs (NOI-PF), non-oncological distal femurs (NOI-DF), oncological proximal femurs (OI-PF), and oncological distal femurs (OI-DF).

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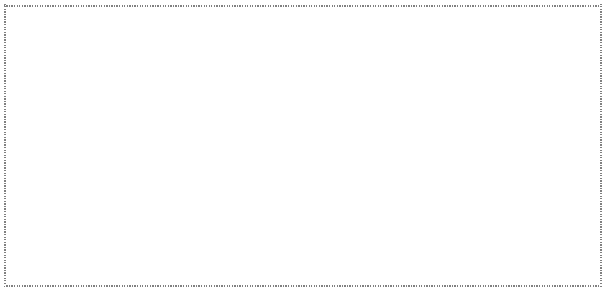

Professeur Christophe NICH

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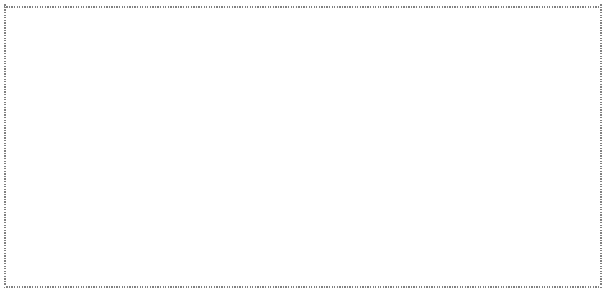
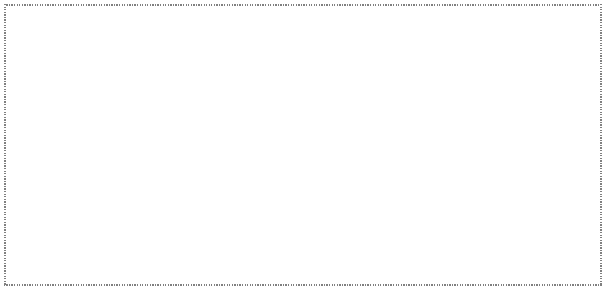


Docteur Vincent CRENN

Vu, le Doyen de la Faculté,



Professeur Pascale JOLLIET

NOM : TRAN PRENOM : Guillaume

Titre de Thèse : Les prothèses massives de fémur en contexte non-oncologique et oncologique. Étude rétrospective sur 189 implants de 2005 à 2020 au CHU de Nantes.

RÉSUMÉ

Introduction : Les prothèses massives sont utilisées dans la gestion des pertes de substance osseuse critiques lors de résections carcinologiques ou de chirurgies non-oncologiques. Nous avons encore peu de recul sur l'usage de ces prothèses dans cette dernière situation. L'objectif de ce travail était donc de comparer le taux de reprise chirurgicale, les complications et le résultat fonctionnel en contexte non-oncologique et oncologique des prothèses massives de fémur.

Méthode : Un total de 189 implants massifs de fémurs proximaux et distaux implantés entre 2005 et 2020 au CHU de Nantes ont été inclus dans cet étude rétrospective. 70 dans le groupe non-oncologique et 119 dans le groupe oncologique. L'étude des reprises chirurgicales et des complications a été réalisé grâce à un modèle de survie à risque compétitif. La nature des complications a été classée selon la classification de Henderson. Les scores fonctionnels ont été cotés selon le score MSTS.

Résultats : Nous ne retrouvions pas de différence significative sur les incidences cumulées de reprises chirurgicales et de complications (HR=0,81 ; IC95% (0,45-1,46) ; p=0,485 et HR=1.27 ; IC95% (0,78-2,06) ; p=0,332 respectivement) entre les indications non-oncologique et oncologique. Il n'y avait pas de différence quant à la nature des complications entre les deux groupes. Sur le plan fonctionnel, les patients en situation oncologique avaient des résultats significativement plus élevés après 10 ans de recul (Non-oncologique = 57.1% ± 22.8 *vs*. Oncologique = 83.1% ± 5.4, p=0.011).

Conclusion : Les prothèses massives de fémurs en condition non-oncologique semblent présenter des résultats similaires en termes de reprises chirurgicales et complications par rapport à celles implantées en condition oncologique. La mise en place d'une étude prospective à grande échelle dans le cadre d'un registre national permettrait de confirmer ces résultats.

Niveau de preuve HAS : Niveau 4, Grade C.

MOTS-CLES

Prothèse massive ; MSTS ; Risque compétitif ; Incidence cumulée