Effect of femoral stem surface coating on clinical and radiographic outcomes of cementless primary total hip arthroplasty: a patient-matched retrospective study

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Abstract
Purpose This study aims to determine whether changing the stem coating grants superior outcomes at a minimum follow-up of five years.

Methods Retrospective review of a consecutive series of primary total hip arthroplasties (THAs) operated by direct anterior approach between 01/01/2013 and 31/12/2014. Two stems were compared, which were identical except for their surface coating; “the Original stem” was fully coated with hydroxyapatite (HA), while “the ProxCoat stem” was proximally coated with plasma-sprayed titanium and HA. Matching was performed. Clinical assessment included modified Harris hip score (mHHS), Oxford hip score (OHS), and forgotten joint score (FJS). Radiographic assessment evaluated alignment, subsidence, pedestal formation, heterotopic ossification, radiolucent lines ≥ 2 mm, spot welds, cortical hypertrophy, and osteolysis.

Results 232 hips received the Original stem and 167 the ProxCoat stem, from which respectively five hips (2.2%) and no hips (0%) underwent revision. Matching identified two groups of 91 patients, with comparable patient demographics. At > five years follow-up, there were no differences in OHS (16 ± 6 vs 15 ± 5; p = 0.075) nor FJS (81 ± 26 vs 84 ± 22; p = 0.521), but there were differences in mHHS (89 ± 15 vs 92 ± 12; p = 0.042). There were no differences in alignment, subsidence, pedestal formation, heterotopic ossification, cortical hypertrophy, and osteolysis. There were differences in prevalence of proximal radiolucent lines (12% vs 0%; p < 0.001) and distal spot welds (24% vs 54%; p < 0.001).

Conclusion At a minimum follow-up of five years, this study on matched patients undergoing primary THA found that ProxCoat stems results in significantly fewer radiolucent lines, more spot welds, and less revisions than Original stems, thus suggesting better bone ingrowth.

Keywords Total hip arthroplasty · Total hip replacement · Cementless stem · Surface coating · Clinical outcomes · Radiographic outcomes

Introduction
The design and surface coating of uncemented femoral stems for total hip arthroplasty (THA) have considerably evolved over the last 30 years to optimise osseointegration [1–3]. Different surface treatments and coatings have been developed to enhance bone ingrowth, including grit-blasting and sand-blasting surface treatments, as well as plasma-sprayed titanium and hydroxyapatite (HA) coatings [4–6].

Hydroxyapatite is one of the most commonly used surface coatings for uncemented stems, with multiple studies reporting good outcomes and survival of these stems in the long term [1, 7, 8]. However, a few recent studies have found no difference in clinical or radiographic outcomes between stems coated with and without HA [9, 10]. Interestingly, few
studies have investigated the effect of other stem coatings on the clinical and radiographic outcomes of THA [11–13]. Combining first a layer of plasma-sprayed titanium and then a layer of HA may prevent HA-delamination, while promoting bone ingrowth into the porous space created by the titanium coating [14].

The senior surgeon of the present study used a titanium-alloy double-tapered stem, fully coated in HA for two years, after which the manufacturer changed the stem coating. Therefore, the purpose of this study is to determine whether changing the stem coating grants superior clinical or radiographic outcomes at a minimum follow-up of five years on a patient-matched cohort.

**Materials and methods**

**Study design and patient selection**

The authors retrospectively reviewed a consecutive series of hips that underwent primary THA between 1 January 2013 and 31 December 2014 at one centre. All patients were operated by the senior surgeon (FL) who systematically performed the direct anterior (Hueter) approach for all primary THAs. The present study included only those hips implanted with either the AMIStem-H (from now on referred to as Original stem) (Medacta, Switzerland) or the AMIStem ProxCoat (from now on referred to as ProxCoat stem) (Medacta, Switzerland), which are identical titanium-alloy double-tapered collarless stems, only varying in their surface coating:

- The Original stem first undergoes a sandblasting process to roughen the entire surface of the stem to 2.5–6 μm; then, it is fully coated with an 80 μm layer of HA (Fig. 1).
- The ProxCoat stem first undergoes a sandblasting process to roughen the entire surface of the stem to 2.5–6 μm; then, the proximal two-thirds of the stem are coated with a 300 μm layer of MectaGrip (unalloyed titanium with a pore size of 100–350 μm) through Air Plasma Spray (APS) technology, and finally the proximal two-thirds of the stem are coated with an 80 μm layer of HA (Fig. 2). Due to the additional layer of coating, the metaphyseal cross-sectional width of the ProxCoat stem is 0.6 mm greater than that of the Original stem.

The type of stem was selected by the surgeon in a non-systematic manner, as the manufacturer gradually reduced supplies of the Original stem and introduced the ProxCoat stem. The surgical technique, including the femoral...
preparation, as well as the instrumentation were identical throughout the study period. This study was approved by the institutional review board of ‘GCS Ramsay Santé pour l’Enseignement et la Recherche’ (IRB: COS-RGDS-2019-12-012-LAUDE-F). Informed consent was obtained from all individual participants included in the study.

**Clinical assessment**

Patients were evaluated pre-operatively by the senior surgeon (FL) using the modified Harris hip score (mHHS; 0, worse; 100, best). The latest evaluation was performed by an independent observer, who recorded the mHHS, Oxford hip score (OHS; 60, worse; 12, best), forgotten joint score (FJS; 0, worse; 100, best), and satisfaction level (very satisfied, satisfied, disappointed, dissatisfied). Complications, re-operations, and revisions were noted.

**Radiographic assessment**

Pre-operative anteroposterior (AP) pelvic radiographs were assessed by the senior surgeon (FL) to evaluate femoral morphology according to Dorr classification [15], canal flare index (CFI) [16], cortical thickness index (CTI) [17], canal bone ratio (CBR) [18], canal calcar ratio (CCR) [19], and morphologic cortical index (MCI) [20] (Fig. 3).

Post-operative AP pelvic and lateral hip radiographs were assessed by two experienced surgeons (MRVG, JS) to evaluate stem alignment (varus/valgus if stem axis > 5° from neutral), stem subsidence (none, < 5 mm and ≥ 5 mm on AP radiographs), pedestal formation, and heterotopic ossification according to the Brooker classification [21]. The canal fill ratio (CFR) was calculated by dividing the femoral stem width by the endosteal diameter width at 5 levels, with the lesser trochanter (LT) as reference point: (i) 2 cm above the tip of the LT, (ii) at the level of the tip of the LT, (iii) 2 cm below the tip of the LT, (iv) 7 cm below the tip of the LT, and (v) 10 cm below the tip of the LT [22] (Fig. 4). Furthermore, the following were assessed on the 14 Gruen zones [23]: radiolucent lines (RLs) (none, < 2 mm, ≥ 2 mm), spot welds (local deposition of new bony trabeculae bridging the endosteal cortex and the stem surface), distal cortical hypertrophy (new bone of cortical density that resulted in an increase in cortical thickness in the central and distal zones: none, slight, moderate, severe), and osteolysis (bone cavitations) [24]. Gruen zones 1, 7, 8, and 14 were considered proximal zones; zones 2, 6, 9, and 13 were considered central zones; and zones 3, 4, 5, 10, 11, and 12 were considered distal zones. A stem was considered loose if there was progressive tilt or if there were RLs ≥ 2 mm along the entire stem; furthermore, subsidence > 5 mm, and/or multiple bone cavitations were considered as highly suggestive signs of loosening [25].

**Statistical analysis**

To enable comparison of outcomes of the Original versus ProxCoat groups, propensity score matching was performed using a logistic regression model, to obtain two similar groups in terms of age, sex, body mass index (BMI), and availability of radiographic follow-up. A 1:1 nearest neighbour algorithm with a calliper of 0.05 was applied to match the patients using their corresponding propensity scores. Descriptive statistics were used to summarise demographic data, clinical scores, and radiographic measurements. For categorical variables, comparisons between groups were performed using Fisher’s tests or chi-squared tests respectively for binary and non-binary variables. Normality of continuous variables was assessed through Shapiro–Wilk tests. For
continuous variables, comparisons between groups were performed using Wilcoxon signed rank tests, as none of the variables were normally distributed. Interobserver agreement was assessed for all radiographic measurements; Gwet’s AC [26] were calculated for categorical variables, and intraclass correlation coefficients (ICC) were calculated for continuous variables, and interpreted as follows: < 0.40 poor; 0.40–0.59 fair; 0.60–0.74 good, and > 0.75 excellent [27]. Interobserver agreement was excellent or good for all radiographic measurements, except for canal bone ratio (ICC = 0.56), Dorr type (Gwet’s AC = 0.56), canal fill ratio at the level 2 cm below the LT (ICC = 0.51), and pedestal formation (Gwet’s AC = 0.58) (Table 1). Statistical analyses were conducted using R, version 4.1.3 (R Foundation for Statistical Computing, Vienna, Austria). P-values < 0.05 were considered statistically significant.

Results

From the initial cohort of 232 hips (220 patients) in the Original group, 54 hips had no radiographic data at a minimum follow-up of five years, 32 hips were lost to follow-up, five hips underwent stem revision for aseptic loosening, and one patient (1 hip) died, thus leaving a study cohort of 140 hips (Fig. 5). From the initial cohort of 167 hips (160 patients) in the ProxCoat group, 40 hips had no radiographic data at a minimum follow-up of five years, 14 hips were lost to follow-up, no hips underwent revision, and one patient (1 hip) died; thus leaving a study cohort of 112 hips. Patients without radiographic data at a minimum follow-up of five years were not recontacted for new radiographs, as the authors did not want to expose them to COVID-19 during the pandemic. It is important to note that the stem revision rate was 2.2% for the Original group (all for aseptic loosening) and 0% for the ProxCoat group (p = 0.078). Propensity score matching resulted in two groups of 91 patients each, with similar patient demographics and pre-operative femoral morphology (Table 2).

Clinical outcomes

The Original group had slightly longer clinical follow-up than the ProxCoat group (6.1 ± 0.7 vs 5.9 ± 0.5 years, p = 0.026) (Table 3). The Original group had slightly worse post-operative mHHS than the ProxCoat group (89 ± 15 vs 92 ± 12, p = 0.042), although there were no significant differences in pre-operative mHHS (49 ± 11 vs 50 ± 10, p = 0.478) and net change in mHHS (40 ± 17 vs 43 ± 14, p = 0.412). Furthermore, there were no significant differences in post-operative OHS (16 ± 6 vs 15 ± 5, p = 0.075), post-operative FJS (81 ± 26 vs 84 ± 22, p = 0.521) and overall satisfaction (very satisfied, 73% vs 84%, p = 0.127).

Complications and re-operations

There were no significant differences in the number of complications that did not require re-operation (5 vs 4, p = 1.000). In the Original group, there was one intra-operative femoral fracture fixed with cerclage wires, one case of dislocation, two cases of iliopsoas tendinopathy, and one case of gluteus tendinopathy. In the ProxCoat group, there was one intra-operative calcar crack which was left untreated, one case of dislocation, one case of superficial wound infection, and one case of post-operative femoral fracture; this patient had a stem subsidence ≥ 5 mm but was not revised.
because the stem was not considered loose. There were no cases of deep venous thrombosis or pulmonary embolism. There were no significant differences in the number of reoperations (2 vs 1, \( p = 1.000 \)). In the Original group, there was one case of recurrent dislocation that underwent cup revision and one case of iliopsoas tendinopathy that underwent endoscopic iliopsoas tenotomy. In the ProxCoat group, there was one case of iliopsoas tendinopathy that underwent endoscopic iliopsoas tenotomy.

### Radiographic outcomes

There were no significant differences in stem alignment, stem subsidence, pedestal formation, heterotopic ossification, cortical hypertrophy, and osteolysis (Table 4). There was a significant difference in canal fill ratio at only one of the five measured levels, at 7 cm below the lesser trochanter (71 ± 25% vs 78 ± 19%, \( p = 0.023 \)). There were significant differences in prevalence and/or distribution of RLs and spot welds. The prevalence of RLs < 2 mm was significantly higher for the Original group compared to the ProxCoat group in the proximal (33 vs 2, \( p < 0.001 \)) and central zones (7 vs 0, \( p = 0.014 \)), but significantly lower in the distal zones (1 vs 10, \( p = 0.009 \)). Furthermore, the prevalence of RLs ≥ 2 mm was significantly higher for the Original group compared to the ProxCoat group in the proximal zones (11 vs 0, \( p < 0.001 \)). The prevalence of spot welds was significantly lower for the Original group compared to the ProxCoat group in the distal zones (22 vs 49, \( p < 0.001 \)).

### Discussion

This study compared two identical titanium-alloy double-tapered collarless stems, which only varied in their surface coating, and found that the Prox Coat stem resulted in better...
radiographic outcomes compared to the Original stem; with significantly fewer RLs and more spot welds, thus suggesting better osseointegration. Furthermore, the ProxCoat stem resulted in fewer femoral revisions compared to the Original stem (0% vs 2.2%), with all Original stems revised due to aseptic loosening. Many studies have reported on outcomes of HA-coated stems [1, 8, 9, 28, 29], but only a few have reported on outcomes of other coatings. Studies on stems with first plasma-sprayed titanium and then HA coating have reported satisfactory mid- and long-term outcomes [6, 30–32], this coating combination may provide stronger biological and mechanical bone fixation compared to only HA coating [6, 33, 34]. A recent study by Liu et al. [35] has shown that a pore size between 50 and 800 μm stimulates bone ingrowth. It is interesting to note that the Original stem had a pore size of 2.5–6 μm, created during the sand-blasting treatment, while the ProxCoat stem had a pore size of 100–350 μm, created during plasma-spray; this could be one of the reasons why the ProxCoat stem resulted in better bone ingrowth.

Table 2  Patient demographics and preoperative radiographic characteristics stratified by stem implanted

|                      | Original (n = 91 hips) | ProxCoat (n = 91 hips) | p-value |
|----------------------|------------------------|------------------------|---------|
| **Mean ± SD**        | **Mean ± SD**          | **Mean ± SD**          |         |
| **Range**            | **Range**              | **Range**              |         |
| **n (%)**            | **n (%)**              | **n (%)**              |         |
| Age at surgery (years) | 59 ± 11               | 60 ± 10                | 0.740   |
| Body mass index (kg/m²) | 25 ± 4                | 25 ± 4                 | 0.794   |
| Female sex           | 41 (45%)               | 40 (44%)               | 1.000   |
| Right operated side  | 46 (51%)               | 49 (54%)               | 0.767   |
| Canal flare index    | 4.2 ± 0.8              | 4.3 ± 0.9              | 0.286   |
| Cortical thickness index | 0.6 ± 0.1              | 0.6 ± 0.1              | 0.150   |
| Canal bone ratio     | 0.4 ± 0.1              | 0.4 ± 0.1              | 0.145   |
| Canal calcar ratio   | 0.4 ± 0.1              | 0.4 ± 0.1              | 0.920   |
| Morphologic cortical index | 2.9 ± 0.5              | 2.8 ± 0.5              | 0.268   |
| Dorr type            | A 22 (24%)             | 15 (16%)               | 0.422   |
|                      | B 60 (66%)             | 65 (71%)               |         |
|                      | C 9 (10%)              | 11 (12%)               |         |

*Patients not asked for radiographs due to COVID-19

Abbreviations: SD standard deviation
Clinical outcomes of uncemented stems reported in the literature have been satisfactory, ranging between 82–97 for HHS and 79–81 for FJS [1, 36–38]. This is consistent with the present study, which reported for the Original and ProxCoat groups respectively, mHHS of 89 ± 15 and 92 ± 12, and FJS of 81 ± 26 and 84 ± 22. It is important to note that even though there were significant differences in radiographic outcomes and revision rates across the two groups, no clinically relevant differences were observed between groups for the functional scores and overall satisfaction. Interestingly, five hips (2.2%) in the Original group underwent stem revision, all due to aseptic loosening, compared to no hips (0%) in the ProxCoat group, thus suggesting that the ProxCoat stem provides better osseointegration. It is important to note that although the difference in revision rates is not statistically significant (p = 0.078), it is clinically relevant. Since revision is a rare event, large cohort studies such as those based on registry data are necessary to ascertain statistical significance. The revision rates of the present study are comparable to those reported in recent literature on uncemented stems for primary THA at similar follow-ups (0–2.4%) [31, 38, 39], with the Original group at the high-end of this range.

The most common complication in the present study was periprosthetic fracture (PPF), which occurred once (1%) in the Original stem group (1 intra-operative), and twice (2%) in the ProxCoat group (1 intra-operative and 1 post-operative). PPF is one of the most common complications in uncemented stems [40, 41]; the rate of PPF reported in other series varied between 0.5 and 12% [40, 42–44], which is comparable to the present study.

Previous studies have shown that surface treatments and coatings may affect the rate of revision of femoral stems. Macheras et al. [45] assessed three types of uncemented stems with similar design but different treatments/coatings: a sand-blasted TiNb-alloy stem, a plasma-sprayed titanium and then HA-coated stem, and a corundum-blasted then HA-coated stem. The authors observed RLs in the proximal and central zones in 4% of the sand-blasted TiNb-alloy stems and these progressed over time, but no RLs were noted in the other two types of stems. The present study includes a detailed radiographic analysis of two matched cohorts. While no significant differences were observed between cohorts at final follow-up for canal fill ratio, stem alignment, stem subsidence, pedestal formation, heterotopic ossification, cortical hypertrophy, and osteolysis; the prevalence and distribution of RLs and spot welds, both markers of osseointegration, were significantly different. It is important to note that RLs ≥ 2 mm were present on 14% of the Original stems versus none of the ProxCoat stems. Furthermore, distal spotwelds were present on 24% of the Original stems versus 54% of the ProxCoat stems, which could also be the result of mechanical discontinuity at the abrupt transition from coated to uncoated zones.

This study has some limitations inherent to its retrospective design. First, patients were not randomised to a type of stem. However, matching resulted in two groups with similar patient demographics and pre-operative femoral morphology. Second, it is difficult to ascertain whether the improved bone growth on ProxCoat stems is due to the additional plasma-sprayed titanium on the proximal two-thirds or due to the removal of HA-coating on the distal third. Third, the minimum follow-up of this study was five years, which is not sufficient to evaluate long-term loosening rates. Fourth, the cohort size and missing radiographic data, as well as the fact that revision rates are a rare event, limit the statistical power of the present study.

### Table 3 Clinical scores stratified by stem implanted

| Clinical follow-up (years) | Original (n = 91) | ProxCoat (n = 91) | p-value |
|----------------------------|------------------|------------------|---------|
| n (%)                      | Mean ± SD        | Range            | Mean ± SD | Range |         |
|----------------------------|------------------|------------------|----------|-------|---------|
| Pre-operative | 49 ± 11          | (15–74)          | 50 ± 10  | (27–75) | 0.478  |
| Post-operative | 89 ± 15          | (42–100)         | 92 ± 12  | (54–100)| 0.042  |
| Net change               | 40 ± 17          | (–20–68)         | 43 ± 14  | (5–68)  | 0.412  |
| Oxford hip score post-operative (60–12) | 16 ± 6        | (12–38)          | 15 ± 5   | (12–34) | 0.075  |
| Forgotten joint score post-operative (0–100) | 81 ± 26        | (0–100)          | 84 ± 22  | (13–100)| 0.521  |
| Overall satisfaction      |                  |                  |          |       |         |
| Very satisfied            | 66 (73%)         |                   | 76 (84%) |       | 0.127  |
| Satisfied                 | 17 (19%)         |                   | 13 (14%) |       |         |
| Disappointed              | 5 (5%)           |                   | 2 (2%)   |       |         |
| Dissatisfied              | 3 (3%)           |                   | 0 (0%)   |       |         |

Abbreviations: SD standard deviation
Table 4 Radiographic outcomes stratified by stem implanted

|                                      | Original (n = 91) | ProxCoat (n = 91) | p-value |
|--------------------------------------|------------------|-------------------|---------|
|                                      | Mean ± SD        | Range             |         |
| Canal fill ratio (%)                 | n (%)            | Mean ± SD         | Range   |
| 2 cm above the lesser trochanter     | 63 ± 6.6         | (52–88)           |         |
| At the lesser trochanter             | 78 ± 7.9         | (60–100)          |         |
| 2 cm below the lesser trochanter     | 83 ± 8.3         | (57–100)          |         |
| 7 cm below the lesser trochanter     | 71 ± 25          | (0–100)           |         |
| 10 cm below the lesser trochanter    | 0 ± 0            | (0–0)             |         |
| Stem alignment                       |                  |                   |         |
| Neutral                              | 68 (75%)         | 69 (76%)          |         |
| Varus                                | 22 (24%)         | 20 (22%)          |         |
| Valgus                               | 1 (1%)           | 2 (2%)            |         |
| Stem subsidence                      |                  |                   | 0.605   |
| None                                 | 87 (96%)         | 88 (97%)          |         |
| < 5 mm                               | 4 (4%)           | 2 (2%)            |         |
| ≥ 5 mm                               | 0 (0%)           | 1 (1%)            |         |
| Pedestal formation                   | 26 (29%)         | 37 (41%)          | 0.119   |
| Heterotopic ossification (Brooker classification) |          |                   |         |
| None                                 | 84 (92%)         | 87 (96%)          |         |
| I                                    | 7 (8%)           | 4 (4%)            |         |
| Radiolucent lines                    |                  |                   |         |
| Proximal zones (GZs 1, 7, 8, 14)     | 35 (38%)         | 2 (2%)            | < 0.001 |
| Central zones (GZs 2, 6, 9, 13)      | 8 (9%)           | 0 (0%)            | 0.007   |
| Distal zones (GZs 3, 4, 5, 10, 11, 12) | 1 (1%)         | 10 (11%)          | 0.009   |
| Radiolucent lines (< 2 mm)           |                  |                   |         |
| Proximal zones (GZs 1, 7, 8, 14)     | 33 (36%)         | 2 (2%)            | < 0.001 |
| Central zones (GZs 2, 6, 9, 13)      | 7 (8%)           | 0 (0%)            | 0.014   |
| Distal zones (GZs 3, 4, 5, 10, 11, 12) | 1 (1%)         | 10 (11%)          | 0.009   |
| Radiolucent lines (≥ 2 mm)           |                  |                   |         |
| Proximal zones (GZs 1, 7, 8, 14)     | 11 (12%)         | 0 (0%)            | < 0.001 |
| Central zones (GZs 2, 6, 9, 13)      | 2 (2%)           | 0 (0%)            | 0.497   |
| Distal zones (GZs 3, 4, 5, 10, 11, 12) | 0 (0%)         | 0 (0%)            | 1.000   |
| Spot welds                           |                  |                   |         |
| Proximal zones (GZs 1, 7, 8, 14)     | 11 (12%)         | 11 (12%)          | 1.000   |
| Central zones (GZs 2, 6, 9, 13)      | 84 (92%)         | 89 (98%)          | 0.169   |
| Distal zones (GZs 3, 4, 5, 10, 11, 12) | 22 (24%)      | 49 (54%)          | < 0.001 |
| Cortical hypertrophy                 |                  |                   |         |
| Central zones (GZs 2, 6, 9, 13)      |                  |                   | 0.311   |
| Slight                               | 5 (5%)           | 7 (8%)            |         |
| Moderate                             | 2 (2%)           | 0 (0%)            |         |
| Severe                               | 0 (0%)           | 0 (0%)            |         |
| Distal zones (GZs 3, 4, 5, 10, 11, 12) | 12 (13%)     | 18 (20%)          | 0.486   |
| Slight                               | 2 (2%)           | 2 (2%)            |         |
| Moderate                             | 0 (0%)           | 0 (0%)            |         |
| Osteolysis                           | 0 (0%)           | 0 (0%)            | 1.000   |

Abbreviations SD standard deviation, GZs Gruen zones
Conclusions

At a minimum follow-up of five years, this study on matched patients undergoing primary THA has shown that changing the stem coating by adding plasma-sprayed titanium before HA and coating only the proximal two-thirds of the stem (ProxCoat) results in significantly fewer radiolucencies and more spot welds, thus suggesting better bone ingrowth. Additionally, the ProxCoat stem resulted in fewer stem revisions compared to the Original stem.

Author contribution All authors contributed to the study conception and design. Material preparation and data collection were performed by MRVG, JS, and FL. Data analysis was performed by SRP and MS. The first draft of the manuscript was written by MRVG and SRP, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Ethics approval All patients provided informed consent for the use of their data for research and publications. The present work was completed after being approved by an institutional review board (IRB: COS-RGDS-2019-12-012-LAUFED-F).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication Not applicable.

Competing interests MRVG, SRP, MS, and JS have nothing to declare. FL declares royalties from Medacta.

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