

Communication

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Communication

Long Term Clinical and Radiographic Osseointegration Outcomes of a Highly Porous 3D-Printed Titanium Collar for Megaprotheses Compared to a Previous Generation HA-Coated Collar

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Simple Summary

Modern endoprosthetic implants often include a collar to help them integrate better with the patient's natural bone, improving stability and reducing loosening. Traditionally, collars coated with hydroxyapatite (HA) have been used, but results have been inconsistent. A new type of collar, made using 3D printing technology, creates a highly porous surface that mimics natural bone structure, potentially enhancing bone growth and attachment. In this study, we compared the long-term performance of these 3D-printed collars to traditional HA-coated ones. We found that the 3D-printed collars led to faster and more reliable bone integration, with fewer cases of loosening, even in higher-risk patients like those with obesity or undergoing complex revisions. These results suggest that 3D-printed collars could improve implant durability and reduce the need for additional surgeries, offering a promising advancement for patients needing large bone replacements.

Abstract

Achieving stable bone integration in megaprosthesis reconstructions remains challenging, with traditional hydroxyapatite (HA)-coated collars showing variable outcomes. This study compares long-term osseointegration and clinical performance of a novel 3D-printed porous collar (EPORE®) versus conventional HA-coated collars in 52 patients (28 with 3D-printed, 24 with HA-coated). Radiographic osseointegration was assessed using a validated scoring system, with follow-up exceeding two years. The 3D-printed group demonstrated significantly higher osseointegration rates (92.9% vs. 70.8%, $p=0.04$) and faster bone ongrowth (470 vs. 1482 days to full integration, $p<0.0001$), with 89.3% achieving the highest integration score compared to 37.5% in the HA group ($p=0.0002$). Notably, no aseptic loosening occurred with 3D-printed collars, while HA-coated collars had an 8% aseptic loosening rate. Despite higher BMI in the 3D-printed group (32.5 vs. 28.4, $p=0.01$), outcomes were superior, suggesting the porous design mitigates obesity-related risks. These findings indicate that 3D-printed collars enhance biological fixation, reduce loosening, and improve implant stability, particularly in complex revisions. This technology represents a significant advancement in megaprosthesis design, with potential to improve long-term outcomes in high-risk patients.

Keywords: megaprosthesis; osseointegration; 3D-printed implants; hydroxyapatite coating; orthopedic reconstruction; porous titanium; implant loosening; bone ongrowth; revision arthroplasty; extracortical fixation

Introduction

Modern endoprosthesis have collars to improve osseointegration with bone. It has been well established that extracortical osseointegration at the collar-bone interface of megaprotheses allowing for better transfer of forces and stresses from the bone to the implant. This is associated with improved implant stability, lower rates of stem fracture and loosening. We had previously published short term results of osseointegration of porous 3D printed collar compared to HA coated collar. The aim of this study was to publish our long-term experience with this novel collar.

Methods: Twenty-eight patients who underwent megaprotheses implantation utilizing the novel collar system were case matched to 24 patients who had previously undergone a HA-coated collar. A minimum radiological follow-up over one year was available in all included patients and minimum 24 months of clinical follow up. Osseointegration was evaluated using postoperative plain radiographs in two planes based on a previously published semi-quantitative score.

Results: Patients in the 3D-printed implant group had a significantly higher mean BMI compared to those in the HA-coated group (32.51 vs. 28.36, $p = 0.01$). The rate of stem loosening was 16% ($n = 4/24$) in the HA-coated group compared to 7% ($n = 2/28$), with both cases of loosening in the 3D printed group related to septic failure. Additionally, the rate of osseointegration was significantly greater in the 3D-printed group (92.9%) than in the HA-coated group (70.8%), ($p = 0.04$). On growth score distribution also differed significantly between groups, with 89.3% of 3D-printed implants achieving the highest on growth score of 4, compared to only 37.5% in the HA-coated group ($p = 0.0002$). These findings suggest that 3D-printed implants may be associated with improved biological integration and structural on growth compared to HA-coated alternatives.

Conclusion: These results suggest that the novel highly porous collar system facilitates faster and more consistent osseointegration at the bone-collar interface compared to the previously used HA-coated collar. A greater proportion of patients demonstrated evidence of successful integration, which was also sustained on longer-term follow-up with less aseptic loosening.

Introduction

Achieving consistent and durable bone integration at the bone prosthesis interface remains a major challenge in megaprosthesis reconstruction [1,2]. Successful osseointegration is essential to reduce aseptic loosening rates by ensuring effective transmission of mechanical stresses across the bone-implant interface [3,4]. While hydroxyapatite (HA)-coated collars have traditionally been used to promote integration, clinical outcomes have been variable, with relatively low and unpredictable osseointegration rates [5–7].

Recent advancements in additive manufacturing have opened new possibilities for implant design [8,9]. In particular, 3D printing technologies now allow for the fabrication of implants with highly controlled porous architectures that closely replicate the morphology of cancellous bone [10]. One such innovation is the EPORE® collar system, which incorporates a titanium scaffold with 100–500 μm interconnected pores, calcium-phosphate coating and trabecular-like structure formed by 350 μm titanium rods.

The design is supported by a growing body of evidence suggesting that such microarchitectures enhance biological fixation [11]. Studies of similar porous implants in revision arthroplasty have reported osseointegration rates of 78–89% at 2-year follow-up [12,13]. Biomechanical evaluations suggest some advantages of this design rationale with greater initial stability through mechanical interlock, enhanced osteoconduction due to optimized pore geometry and long-term fixation through progressive bone ingrowth [14].

Our initial findings at one year follow up confirmed these theoretical benefits, showing faster and more consistent osseointegration with porous collars compared to conventional HA-coated designs [15]. This study builds on those preliminary results by evaluating longer-term clinical outcomes. The results have significant implications for implant selection, particularly in revision settings where reliable osseointegration is critical.

Methods

This retrospective study included 52 patients (28 in the EPORE group and 24 in the HA collar group) with a minimum follow-up of 2 years. All patients had regular follow up with x-rays done in at least 2 planes post op. In all cases, fellowship-trained orthopaedic surgeons with longstanding experience in the use of megaprotheses for oncology and revision arthroplasty performed the surgery from a single specialist centre.

Osseointegration was graded using a previously published semi-quantitative scale [5]. Bone ongrowth was assessed by analysing two bone-collar interfaces on the ap (anteroposterior) and lateral x-rays, respectively. The final available set of x-rays were graded. All cases were independently evaluated by two rates and consensus was reached in all cases. Grade 1 represents no visible ongrowth on all four interfaces, grade 2 indicates bony overgrowth with gap formation, grade 3 has osseointegration in one or two interfaces and grade 4 means visible ongrowth on a least three interfaces. Clinical records were analysed and variables including revision surgeries and complications were collected.

Statistical Analysis

Data are given as mean $\pm$ standard deviation (SD). Number and percentage were reported for categorical data.

Categorical variables with groups were compared using the Fisher's exact test, and the chi-square test. The t-test was utilized to compare continuous variables between two groups. The Kaplan–Meier plot with log-rank test was used to compare the survival curves. A p value <0.05 was considered statistically significant for all employed tests. Data was analysed and visualized using SPSS (Version 25.0, IBM, Armonk, NY, USA) and GraphPad Prism (Version 9, GraphPad Software, La Jolla California USA).

Results

We included 52 patients in this study, with 24 patients (46.15%) receiving HA-coated prostheses and 28 patients (53.84%) receiving 3D-printed prostheses. Pre-operative and perioperative demographic data are presented in Table 1. The cohort comprised 24 females (46.15%) and 28 males (53.84%), with no statistically significant difference in sex distribution between groups (HA-coated: 58.33% female; 3D-printed: 35.71% female; $*p=0.11$). The mean age across all patients was 65.2 years (range: 17–95), with comparable ages between the HA-coated (mean 63.8 years, range 17–86) and 3D-printed groups (mean 66.7 years, range 32–95; $*p=0.42$). However, the mean BMI differed significantly between groups (HA-coated: 28.36, range 17.6–37; 3D-printed: 32.51, range 20.1–38.7; $*p=0.01$). Demographic characteristics were otherwise balanced, with no further statistically significant differences observed between cohorts.

The Charlson Comorbidity Index (CCI) served as a valuable tool to objectively quantify and compare baseline comorbidity burdens between our study groups [16]. As a validated and widely adopted metric in orthopaedic and oncologic research, the CCI provided a standardized approach to assess prognostic comorbidities that could influence surgical outcomes. Our analysis revealed well-balanced cohorts, with comparable mean CCI scores between the HA-coated (3.6, range 1–6) and 3D-printed collar groups (3.96, range 0–8, $p=0.43$). This similarity in comorbidity profiles strengthens the validity of our comparative outcomes analysis, as it suggests that any differences in osseointegration are unlikely to be driven by disparities in patients' underlying health status. Similarly, there was no significant difference in the incidence of perioperative chemo or radiotherapy in the two groups being compared.

However, there was a significant difference in the anatomical location of implants ($p = 0.016$). The HA-coated group primarily received proximal femur replacements (66.7%), while the 3D-printed group had more distal femur implants (64.3%). Proximal tibia replacements were rare overall.

In all 3D-printed collar cases cement fixation of the stem was used compared to 67% of cases in the HA collar group. The most common indications for surgery were periprosthetic joint infection (38.46%) and revision arthroplasty (34.62%). Other indications included primary malignancy (19.23%) and bone metastases (7.69%). The distribution of surgical indications did not significantly differ between groups (p=0.21).

The results of our post-operative outcomes are shown in Table 2. The overall mean follow-up duration was 1125 days (±668). Patients in the HA-coated collar group had a significantly longer follow-up period (1326 ± 525 days) compared to those in the 3D-printed collar group (925 ± 287 days). This difference was statistically significant (p=0.002, t-test) and likely due the HA-coated collar prostheses having been in use for a longer time duration.

The 3D printed collars (92.86%) showed better osteointegration on long term follow up when compared to HA coated collars (70.83%) and the difference was statistically significant (p<0.04). There was more grade 1 and grade 3 cases in the HA-collar cohort while grade 4 cases were more prevalent in the 3D-printed collar group. The percentage of patients with grade 4 osteointegration was statistically significant in the 3D printed group(p<0.001). Figure 1 demonstrates the ongrowth score results for both groups.

The patients in the 3D-collar cohort reached their final ongrowth score (grade 4) faster when compared to the HA-collar cohort (470±71 days vs. 1482±105 days, p<0.0001) and this was confirmed using the Kaplan Meier analysis (Figure 2).

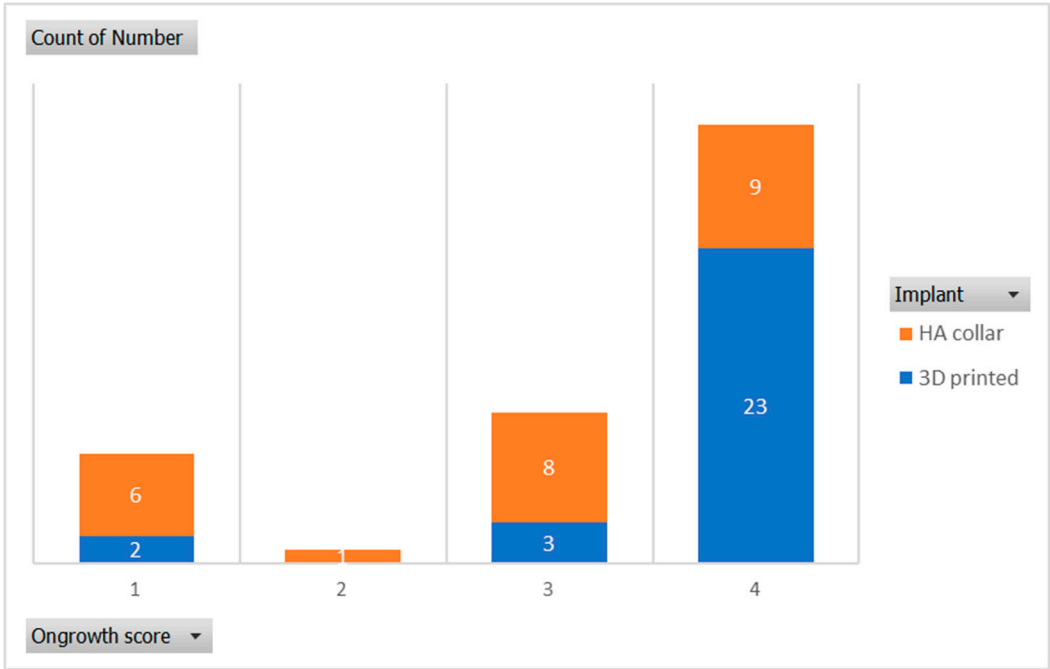
There were 6 cases of stem loosening, 4 in the HA collar group and 2 in the 3D printed group. Both cases of loosening in the 3D printed group were associated with periprosthetic joint infection. The rates of aseptic loosening were 8% (n=2/24) in the HA group compared to 0% in the 3D printed group.

Table 1. Demographic characteristics of both study cohorts.

Variables	Overall (n=52)	HA-coated (n=24)	3D-printed (n=28)	p value
Female (n%)	24 (46.15)	14(58.33)	10(35.71)	0.16
Male (n%)	28 (53.84)	10(41.67)	18(64.28)	
Age, mean(range)	65.2(17-95)	63.8 (17-86)	66.7 (32-95)	0.876)
BMI, mean(range)	30(17.6-38.7)	28.36 (17.6 -37)	32.51 (20.1-38.7)	0.01
CCI, mean(range)	3.8(0-8)	3.6 (1-6)	3.96 (0-8)	0.43
Previous revision surgery (n%)	38 (73.1)	16 (66.67)	22(78.57)	0.36
Peri chemo (n%)	7(13.46)	3(12.5)	4(14.29)	1.00
RT (n%)	1(0.19)	1(0.41)	0(0)	0.46
Indication (n%)				
Revision				
arthroplasty	18(34.62)	6(25)	12(42.86)	
Periprosthetic				
infection	20(38.46)	10(41.66)	10(35.71)	0.21
Primary	10(19.23)	7(29.16)	3(10.71)	
Malignancy	4(7.69)	1(4.16)	3(10.71)	
Bone metastasis				
Type of implant (n%)				
Proximal femur	25(48.07)	16(66.66)	9(32.14)	0.016
Distal femur	26(50)	8(33.33)	18(64.28)	
Proximal tibia	1 (1.9)	0	1 (0.3)	
Cement fixation (n%)	44(84.61)	16(66.66)	28(100)	0.002

Table 2. Post-operative outcomes.

variables	Overall (n=52)	HA-coated (n=24)	3D-printed (n=28)	p value
Follow up days mean (SD)	1125(=/-668)	1326(+/-525)	925(+/-287)	0.002
Osseointegration yes/no (n%)	43(82.69)	17(70.83)/7(29.16)	26(92.86)/2(0.71)	0.04
Ongrowth score (n%)				
1	8(15.3)	6(25)	2(7.14)	0.12
2	1(1.9)	1(4.1)	0(0)	0.46
3	11(21.15)	8(33.3)	3(10.7)	0.08
4	32(61.5)	9(37.5)	23(82.14)	0.001
Stem loosening (n%)	6(11.53)	4(16.66)	2(7.14)	0.38



X axis – Ongrowth scores 1-4.
Y axis Implants used HA/3D Epore collar

Figure 1. Distribution of ongrowth scores among both study groups. The distribution of ongrowth scores differed significantly between the two groups. The HA-collar cohort had a higher proportion of grade 1 and grade 3 cases, whereas the 3D-printed collar group showed a greater prevalence of grade 4 osteointegration. The difference in the percentage of patients achieving grade 4 ongrowth was statistically significant ($p < 0.001$), indicating superior bone integration in the 3D-printed collar group compared to the HA-collar group.

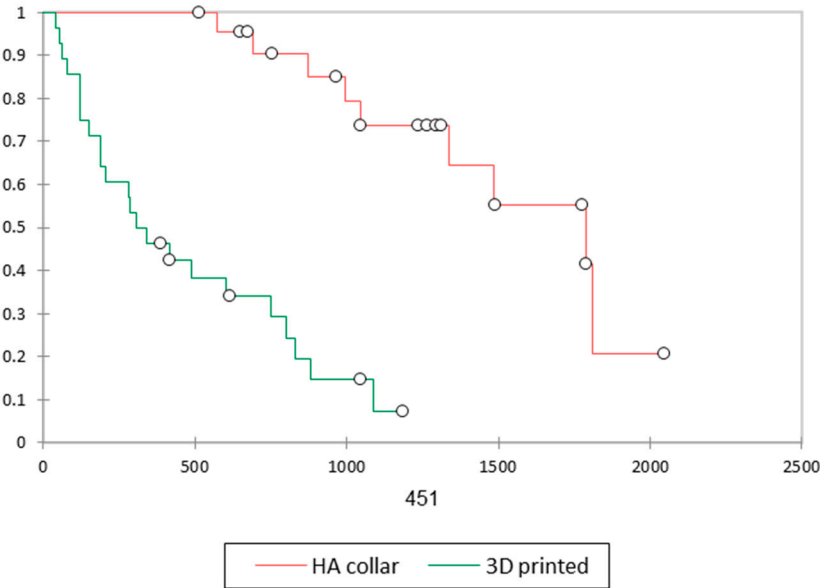


Figure 2. KM curve showing time to ongrowth score 4 distributions between two groups. Kaplan-Meier analysis demonstrated a significant difference in time to achieve ongrowth score 4 between the two groups, with the e-pore collar group showing faster and more frequent ongrowth attainment compared to the HA collar group (log-rank $p < 0.05$). This suggests enhanced osseointegration or earlier bone formation in the e-pore collar cohort.

Discussion

To our knowledge, this is the first long-term follow-up study to assess the clinical results and osseointegration capacity of this novel highly porous 3D-printed collar (EPORE®) demonstrating superior osseointegration rates and mechanical stability with the novel design. These implants are often deployed in complex clinical settings, including oncologic resections and revision arthroplasty, where the risk of complications such as aseptic loosening remains high. Despite the inherent complexity of cases the 3D-printed collar achieved 92.86% osseointegration, significantly outperforming the HA-coated group (70.83%, $*p < 0.04$). This aligns with our earlier findings at 1 year and reinforces the collar’s capacity to foster robust extracortical bridging, even in biologically challenging scenarios. Notably, the 3D-printed cohort exhibited faster and more complete bone ongrowth.

The superior performance in higher BMI patients (mean 32.51 in 3D-printed group) challenges conventional wisdom about obesity and implant fixation. Though there have been no formal studies, but higher loosening rates of loosening have been noted in obese patients with standard arthroplasty implants.[17] Hence our results suggest that optimized surface topography may mitigate this risk. This finding warrants further investigation given the increasing prevalence of obesity in patients.

We found 6 cases of stem loosening in total, 2 in the 3D collar group on the background of a periprosthetic joint infection requiring further surgical interventions, due to infection. There compared to 4 cases of aseptic loosening in the HA collar group suggests that effective integration reduces aseptic loosening as per previous clinical and biomechanical studies. The absence of aseptic failures in our 3D-printed cohort (with both loosening cases being infection-related) supports the biomechanical hypothesis that extracortical osseointegration reduces stress concentrations at the stem-cement-bone interface. [18,19].

The 3D printed collar group performed well in revision cases and revision arthroplasty as well. Three key findings warrant emphasis: First, the 3D collar's time-to-integration advantage (173 vs. 299 days) persisted long-term, with 82% maintaining Grade 4 osseointegration at 2 years versus 37.5% for HA-coated collars ($p < 0.001$). This aligns with biomechanical studies showing porous titanium's superior osteoconductivity, where pore sizes of 100-500µm promote vascular invasion and bone

deposition [20,21]. Second, while cemented fixation showed numerically better outcomes in both groups, the 3D collar's performance remained superior regardless of fixation method in the HA group, indicating its design rather than surgical technique, to avoid cement at bone-collar interface, drives integration success.

Notably, our results contrast with historical data reporting $\leq 50\%$ osseointegration with HA collars in revision cases [5]. The 3D collar achieved 85% integration even in revision arthroplasty - a population where prior studies found only 27% success [5]. This has important implications for managing aseptic loosening, where reliable extracortical fixation could reduce stem stress shielding.

Several limitations must be acknowledged. The follow-up discrepancy (925 vs 1326 days) reflects the newer technology's introduction timeline. However, the consistency of our radiographic outcomes across time points strengthens their validity. The anatomical distribution difference (more distal femoral replacements in 3D-printed group) introduces potential confounding. However as distal femur reconstructions typically experience higher mechanical stresses, the 3D-printed collar's performance in these theoretically higher-risk cases strengthens the clinical significance of our findings. Future prospective studies should correlate these findings with functional outcomes and implant survivorship.

Conclusion

The 3D-printed porous collar represents a significant advancement in megaprosthesis design, offering faster and more reliable osseointegration. This is particularly valuable in complex revisions where biological fixation is most challenging and appears to translate into reduced aseptic loosening rates in our series.

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