Trabecular metal collars in endoprosthetic replacements: do they osseointegrate?

From Glasgow Royal Infirmary, Glasgow, UK

Correspondence should be sent to E. Fraser ewen.fraser3@nhs.scot

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E. Fraser,[1] S. Spence,[2] O. M. Farhan-Alanie,[3] J. Doonan,[4] A. Mahendra,[4] S. Gupta[4]

[1]Ninewells Hospital, Dundee, UK
[2]Royal Alexandra Hospital, Paisley, Scotland
[3]The Royal Orthopaedic Hospital NHS Foundation Trust, Birmingham, UK
[4]Glasgow Royal Infirmary, Glasgow, UK

Aims
Limb salvage surgery (LSS) is the primary treatment option for primary bone malignancy. It involves the removal of bone and tissue, followed by reconstruction with endoprosthetic replacements (EPRs) to prevent amputation. Trabecular metal (TM) collars have been developed to encourage bone ingrowth (osseointegration (OI)) into EPRs. The primary aim of this study was to assess whether OI occurs when TM collars are used in EPRs for tumour.

Methods
A total of 124 patients from July 2010 to August 2021 who underwent an EPR for tumour under the West of Scotland orthopaedic oncology team were identified. Overall, 81 patients (65%) met the inclusion criteria, and two consultants independently analyzed radiographs at three and 12 months, as well as the last radiograph, using a modified version of the Stanford Radiological Assessment System.

Results
OI of the TM collar occurred in approximately 65% of patients at last radiograph. The percentage of patients with OI at three months (65.4%) reflected the 12-month (65%) and long-term (64.4%) follow-up. The median amount of OI across all radiographs was one at all three timepoints, with only five cases (11.1%) showing OI in all four zones at last radiograph. Radiolucency at the bone:collar junction was present in 23 cases (28.4%) at three months, but only four (6.7%) showed progression of this at 12 months. The interobserver reliability was found to be highly reliable in all parameters ($p < 0.001$).

Conclusion
OI occurs in approximately 65% of TM collars, and is similar at three months, 12 months, and last radiograph. The extent of OI at the bone:collar junction was found to have decreased at longer-term follow-up. Furthermore, radiolucency at the bone-collar impact junction does occur in some patients but only a low number will show radiolucency progression at longer-term follow-up.

Take home message
- Osseointegration (OI) seen in patients with trabecular metal (TM) collars at short-term follow-up will be reflected at longer-term follow-up. TM collars do osseointegrate, but not to the same extent as hydroxyapatite collars.
- Radiolucency may occur at early follow-up; however low numbers progress, and in the absence of infection, radiolucency may not necessitate revision surgery.

Introduction
Bone resection with reconstruction is a well-recognized treatment used for primary/secondary bone and haematological malignancy.[1,2] Limb salvage surgery (LSS) is the removal of bone and tissue followed by reconstruction to save a limb and prevent amputation. The three main aims of LSS in malignancy cases are to provide stability, enable weightbearing, and facilitate ambulation.[3]

Bone & Joint Open

Endoprosthetic replacements (EPRs) have been developed to provide an alternative option to amputation with positive results. LSS has several advantages when compared with amputation: limb function/anatomical alignment is maintained; it provides a psychological benefit to patients; and the overall cost is thought to be cheaper.[4,5] LSS is now the primary treatment option for distal femur tumours requiring resection,[5] and in osteosarcoma patients, 85% to 90% will undergo LSS.[1]

Trabecular metal (TM) is a tantalum biomaterial that has been used for dental treatment, and primary and revision arthroplasty.[6-9] It is porous in nature, which allows for osseointegration (OI; bone ingrowth into a metal implant) and increased biological fixation when used in upper and lower limb arthroplasty, with better outcomes for TM seen in revision surgery.[8,10-13] TM collars (Figure 1)[14] are circumferential and attach to the bottom or top of the prosthesis dependent on the EPR location. The TM collar is the first part of the EPR construct to sit atop cortical bone and it is hoped that it will create a firm fixation through bone:prosthesis integration. The collars come in three sizes (25 mm, 30 mm, and 35 mm), while the intramedullary stems vary from 9 mm to 19 mm in diameter.[14] Several studies have shown that aseptic loosening is a major complication associated with LSS with varying rates of success in five- to ten-year follow-up.[15-17] The rate of loosening in distal femoral prostheses was reported to be between 3% and 29% at four- to ten-year follow-up.[18]

The materials used to encourage OI have been mainly alloys including hydroxyapatite (HA), cobalt-chromium, and titanium. When compared with TM, all have been found to have deficiencies, including reduced porosity, elasticity, and frictional characteristics.[19,20] A thorough literature search found several studies that looked at various collar materials in EPRs for bone tumour;[21–23] however, there is no published work solely looking at TM collar use in EPR for tumour. This study is thought to be the first of its kind.

The primary aim of this study was to assess if radiological OI occurs when TM collars are used in lower limb EPRs. The secondary aims were to assess how long OI takes to occur, and whether the Stanmore Radiological Assessment System (SRAS)[21] can predict the success or failure of OI.

Methods

Data were gathered from a prospectively collected musculoskeletal oncology database used by the West of Scotland (WoS) orthopaedic oncology team. All patients who underwent an EPR for a bone tumour under the WoS team between July 2010 and August 2021 were identified and vetted through strict inclusion and exclusion criteria. Ethical approval was not required; however, data were gathered with trust Caldicott approval.

The inclusion criteria for this study were: any patient who received an EPR for bone tumour; the patient received a lower limb EPR with a TM collar; and the periprosthetic implant must have been a Zimmer EPR (Zimmer Biomet, UK). The exclusion criteria were: the patient died prior to the three-month radiograph; the patient was treated for infection or imaging was suspicious of infection; a total femur Zimmer EPR was used (does not use a TM collar); there was insufficient radiological imaging of implant; or follow-up was lost or refused by patient.

Radiological analysis

Radiograph analysis was carried out using Picture Archiving Communication System software (Carestream VUE PACS, USA). Pertinent radiographs (anteroposterior (AP) and lateral) were analyzed at three months, 12 months, and last appointment. A modified version of the SRAS was used to assess four different parameters:

1. Radiolucent line score: extracortical bone and implant collar (RLBC).
2. Bone:shoulder implant junction score (BSIJ).
3. Radiolucent line score: cemented intramedullary fixation (RLCI).
4. Osseointegration score (OIS).

The first modification we made was measuring RLBC with a binary response, "yes" indicating at least one zone of radiolucency instead of the previous quantitive assessment. Second, we assessed for any cortical bone loss at the BSIJ in a binary fashion, rather than measure the distance in millimetres.

All parameters were assessed at the stated timepoints by two orthopaedic oncology consultants (AM, SG). To reduce assessment bias, radiographs were graded independently and, if different, an average of the two was taken. Where the score was yes/no, or not a whole number (e.g. 2.5), the score from the first observer (SG) was taken.

Radiolucent line score: extracortical bone and implant collar

Each collar region was divided into four parts: anterior, posterior, medial, and lateral. If a radiolucent line was seen in any of the four quadrants, it was deemed that OI had not occurred at the TM collar, shown in Figure 2. Therefore, a radiolucent line in any quadrant would score as 'yes'; if no line was seen, this would be scored as 'no'.

Bone:shoulder implant junction score

This is the distance that separates bone from the shoulder of the implant located directly above the transection site. Each observer assessed for evidence of gapping in this region; the result was either yes or no. Progression of the gap compared with the previous timepoint was scored as yes; however, a gap with no progression was scored as no.

Radiolucent line score: cemented intramedullary fixation

Each radiograph was assessed for radiolucency along the length of the intramedullary (IM) stem. The stem was divided into six equidistant zones and separated into anterior, posterior, medial, and lateral parts. A radiolucent line was scored as one and no radiolucency was scored as zero, with a maximum of 24 points available per radiograph. A total of 24 points represents an IM stem totally encompassed by radiolucency (Figure 3).

Osseointegration score

OI score (OIS) was defined as bony growth over the side of the TM collar with no evidence of radiolucency between bone and implant (Figure 4). AP and lateral radiographs were assessed for OI with each collar divided into four parts (anterior, posterior, medial, and lateral). Each part scored one point if OI had occurred, with a maximum of four points available.

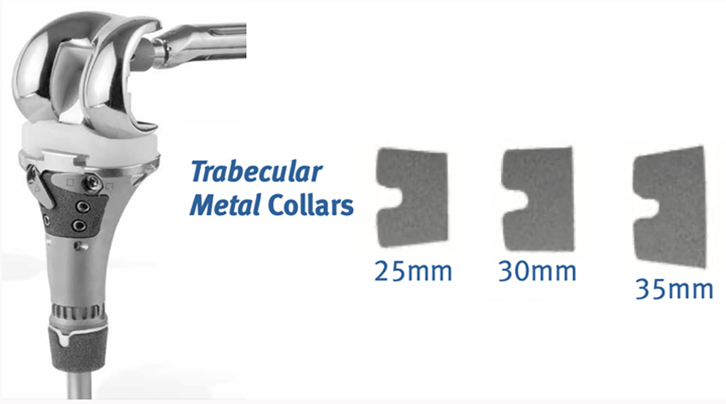

Fig. 1
Zimmer Segmental proximal tibial replacement and associated trabecular metal collars.

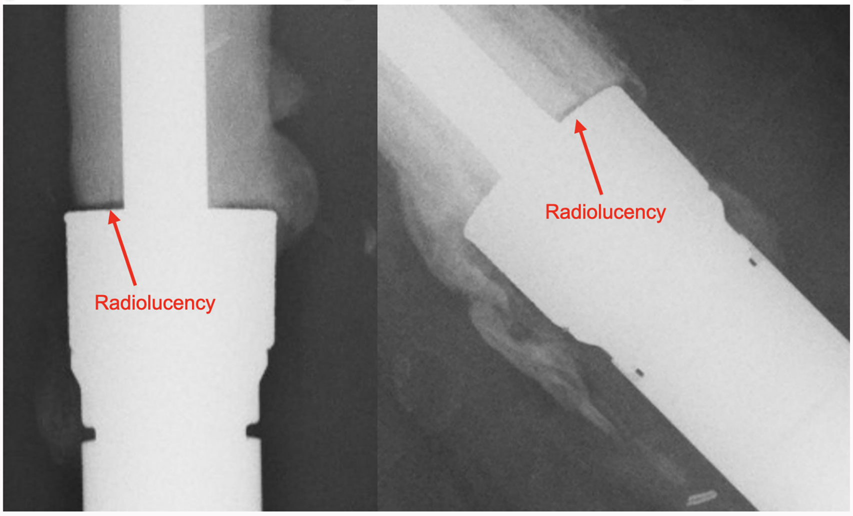

Fig. 2
Radiolucent line score: extracortical bone and implant collar in anteroposterior and lateral images.

Statistical analysis

Descriptive analysis was carried out to assess demographical data and simple statistics. Interobserver reliability was assessed using Cohen's kappa coefficient (κ) for RLBC and BSIJ, and Spearman's rank-order correlation (r) for RLCI and OIS. Chi-squared test was used to compare RLBC timepoints against each other; the same was done for BSIJ. Welch's *t*-test was used to compare RLCI time points, and the Mann-Whitney U test compared OIS at different timepoints. SPSS software v. 25 (IBM, USA) was used for all statistical analysis.

Results

Patient demographics

Between July 2010 and August 2021, 124 patients underwent an operation for an EPR. A total of 81 patients (65.3%) met the inclusion criteria and 43 patients (34.7%) were excluded, as displayed in Table I.

The median patient age was 56 years (IQR 30 to 82), with 52 males (64.2%) and 29 females (35.8%). The dataset range had a low of three months (minimum length needed for inclusion) and a high of 132 months. Figure 5 shows that at three months, 81 patients had radiographs; 60 (74.1%) had imaging at 12 months; and 45 (55.6%) had radiographs after 12 months. The mean follow-up at last radiograph was 33 months (3 to 132), with a median of 24 months (IQR 6 to 60).

Tumour characteristics

The most common site of malignancy was the femur (n = 72, 88.9%), with all tumour locations shown in Table II. All cases had their histology analyzed and were categorized into benign, haematological, metastasis, and sarcoma (Table III). Sarcoma was the most prevalent histological finding with 41 cases (50.6%) identified.

Interobserver reliability

The data collected showed excellent interobserver reliability between the two consultants conducting scoring (Table IV). The RLBC and BSIJ were assessed with Cohen's kappa test. All timepoints, except RLBC last image, were found to be in almost perfect agreement ($\kappa > 0.81$) and statistically significant ($p < 0.001$). The RLBC last image had a κ value of 0.722 which is classed as a moderate level of agreement ($p < 0.001$). The RLCI and OIS were assessed for interobserver reliability using

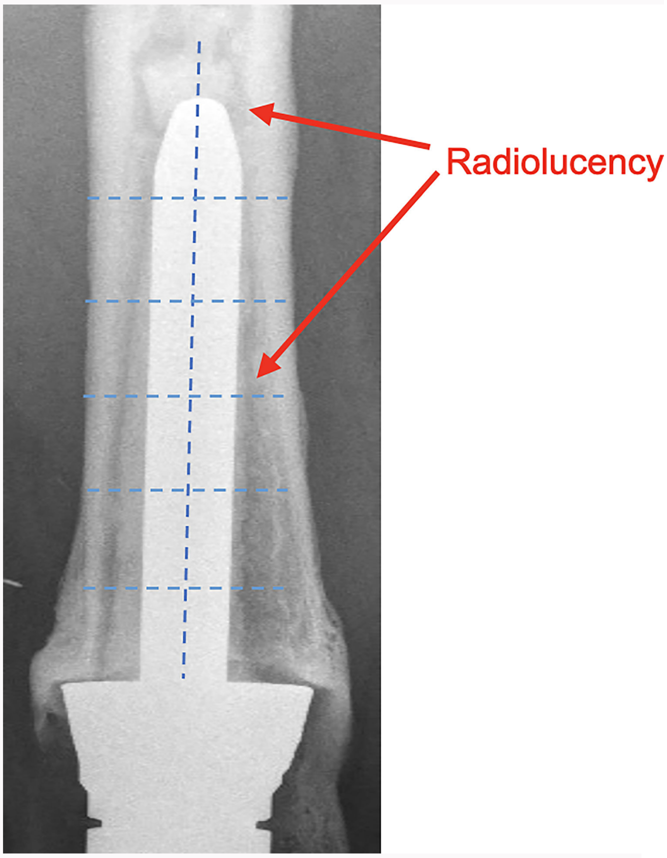

Fig. 3
Radiolucent line score: cemented intramedullary fixation.

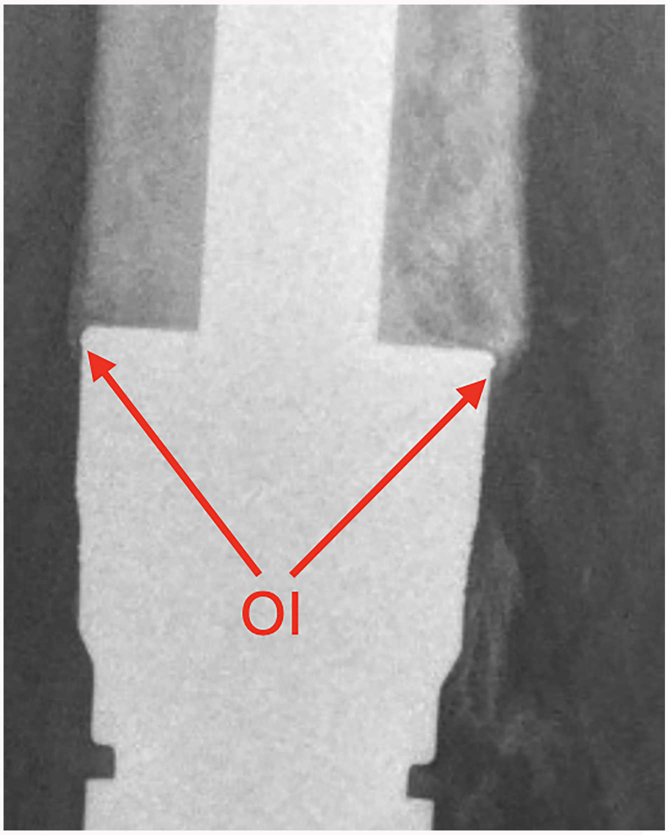

Fig. 4
Osseointegration (OI) score.

Table I. Reasons for exclusion.

Exclusion criteria	N (%)
Upper limb	13 (30.2)
Only immediate postoperative radiographs	10 (23.3)
Different implant	5 (11.6)
Infection	5 (11.6)
Imaging inadequate	2 (4.7)
No three-month radiograph	2 (4.7)
Total femur implant, so no TM collar used	2 (4.7)
No follow-up scans	1 (2.3)
Not used for tumour	1 (2.3)
Postoperative mortality	1 (2.3)
Patient refused follow-up	1 (2.3)
Total	43 (100.0)

TM, trabecular metal.

Spearman's rank-order correlation. All timepoints were found to have a strong positive correlation ($r > 0.81$) and statistically significant ($p < 0.001$).

Radiolucent line score: extracortical bone and implant collar
The RLBC at three months showed that radiolucent lines were present in 23 patients (28.4%). By 12 months, 21 patients (35%) had radiolucent lines, and at last radiograph, ten (22.2%) had radiolucent lines present (Table V). None of these cases underwent any revision surgery for signs of aseptic loosening. Chi-squared test was used to compare the data points. The only significant difference found was between 12 months and last radiograph ($p = 0.026$).

Bone shoulder implant junction score
The BSIJ at three months was the same result ($n = 23$) as RLBC at three months due to these radiographs showing new radiolucent lines from the postoperative radiographs. The images at 12 months showed progression from the images at three months in four radiographs (6.7%). The last radiographs showed that seven cases (15.6%) had increased radiolucency from the previous imaging at 12 months (Table V). Chi-squared test was used to compare the data points and a significant difference was found between the three- and 12-month radiographs ($p = 0.010$).

Radiolucent line score: cemented intramedullary fixation
The RLCI at three months found no stem radiolucency in any of the radiographs. At 12 months, two images showed radiolucency with a mean of three out of 24 zones affected (SD 1.41). At last radiograph, eight cases exhibited radiolucency along the stem, with a mean of ten (1 to 24) zones affected. Figure 6 shows the extent of radiolucency in affected stems. The difference between three months and last radiograph,

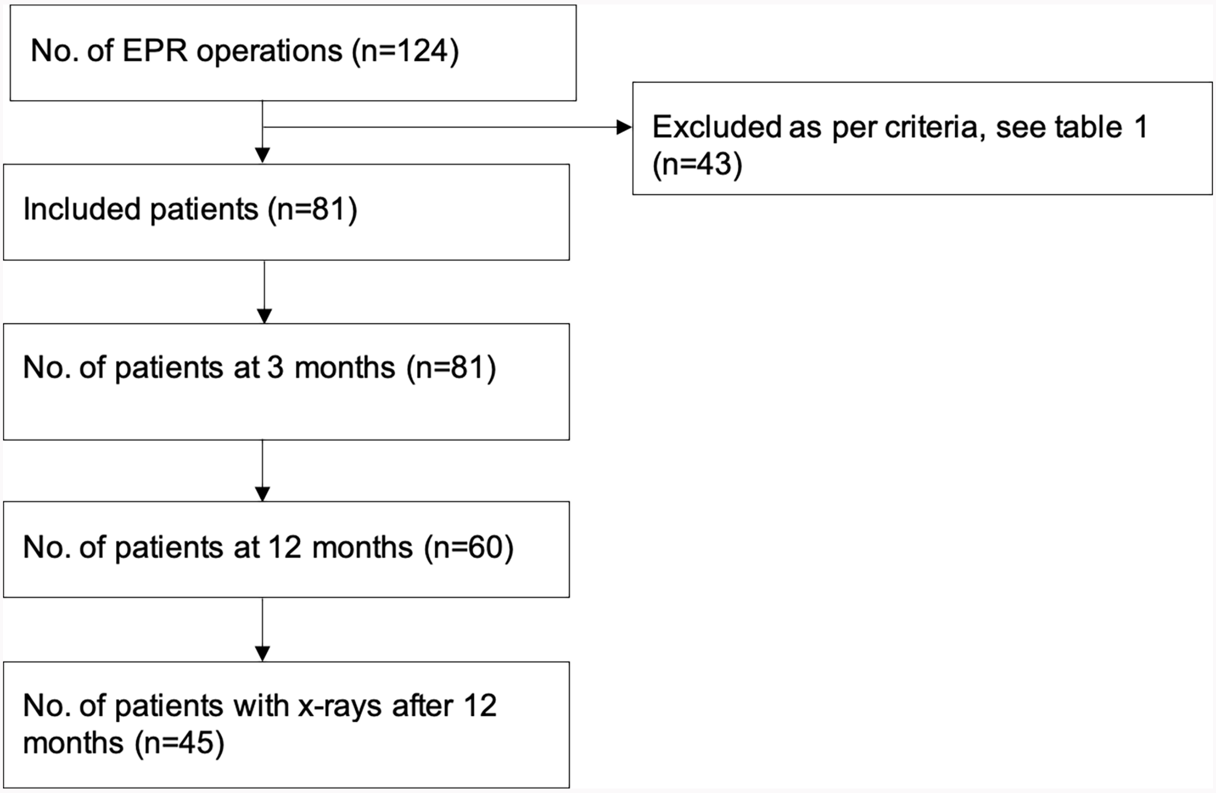

Fig. 5
Follow-up flowchart. EPR, endoprosthetic replacement.

Table II. Location of tumour.

Location	N (%)
Femur	72 (88.9)
Tibia	3 (3.7)
Pelvis	3 (3.7)
Fibula	1 (1.2)
Knee	1 (1.2)
Location unknown	1 (1.2)
Total	81 (100.0)

Table III. Histology of cases.

Histology	N (%)
Benign	7 (8.6)
Haematological	5 (6.2)
Metastasis	28 (34.6)
Sarcoma	41 (50.6)
Total	81 (100.0)

and 12 months and last radiograph, were both found to be statistically significant with Welch's *t*-test ($p = 0.034$ and 0.045, respectively). Of the seven cases that showed stem radiolucency, none had undergone any revision procedure for possible aseptic loosening. It should also be noted that cases of infection that would have shown radiolucency around the stem had already been excluded.

Osseointegration

OI was seen in 53/81 cases (64.4%) at three months, 39/60 cases (65.0%) at 12 months, and 29/45 (64.4%) at last radiograph. Table VI shows that despite decreasing numbers at mid- and long-term follow-up the percentage of cases showing OI remains relatively stable.

Of the patients who did not osseointegrate, there was an approximate split between male and female patients at all three timepoints (three months M 14: F 14; 12 months M 12: F 9; and last radiograph M 8: F 8). In those who did osseointegrate, the percentage reflected that of the initial split (64% M: 36% F) of male to female patients (three months, M 38 (72%): F 15 (28%); 12 months, M 28 (72%): F 11 (28%); and last radiograph, M 20 (69%): F 9 (31%).

The median OIS of all radiographs was one at all three timepoints. When looking at OIS for radiographs only showing osseointegration, the median score was two at all three timepoints.

Discussion

TM collars osseointegrate, but not at the levels reported by alternative collars of different materials for the same use. OI of at least one zone inferred a stable construct; this occured in approximately 64.4% of cases. In some cases, a radiolucent line

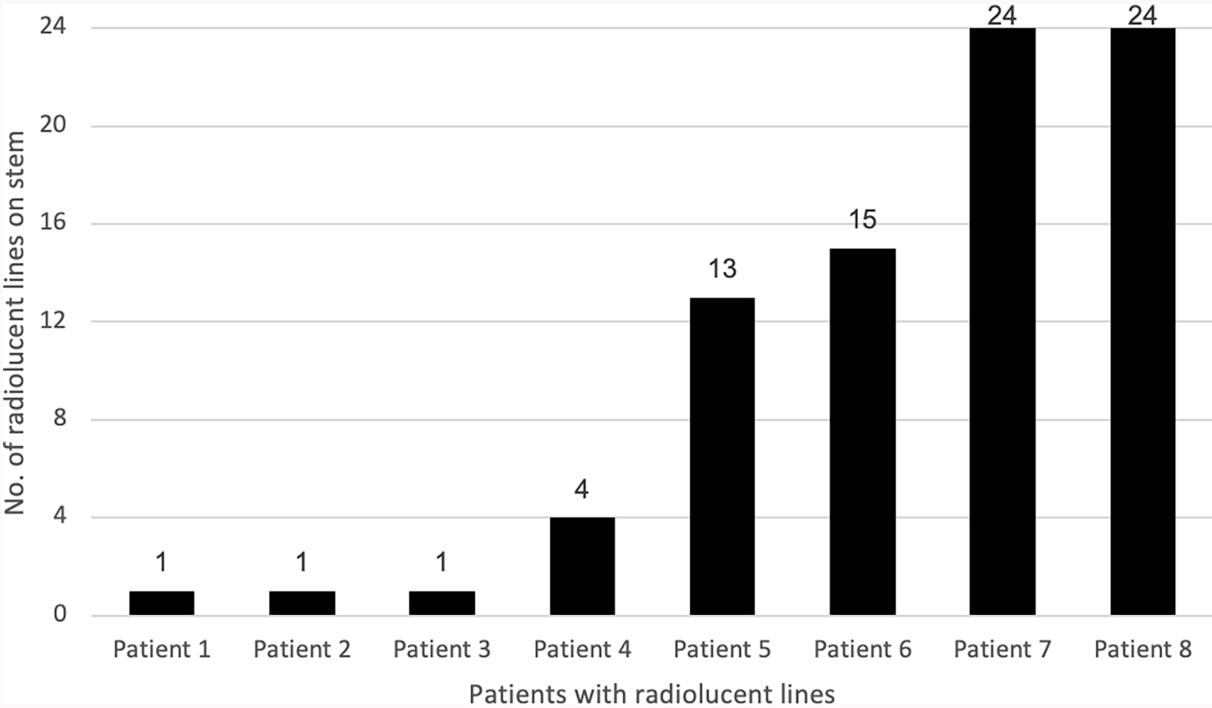

Fig. 6
Level of radiolucency per patient affected at last radiograph.

Table IV. Interobserver reliability of the four different parameters.

Period	RLBC, kappa	p-value	BSIJ, kappa	p-value	RLCI, Spearman's rank order correlation	p-value	OIS, Spearman's rank order correlation	p-value
3 months	1	< 0.001	1	< 0.001	1	< 0.001	0.961	< 0.001
12 months	1	< 0.001	0.88	< 0.001	1	< 0.001	0.957	< 0.001
Last radiograph	0.722	< 0.001	0.91	< 0.001	1	< 0.001	0.777	< 0.001

BSIJ, bone:shoulder implant junction score; OIS, osseointegration score; RLBC, radiolucent line score: extracortical bone and implant collar; RLIC, radiolucent line score: cemented intramedullary fixation.

Table V. RLBC and BSIJ scores.

Period	RLBC = yes	BSIJ = yes
3 months, n (%)	23 (28.4)	23 (28.4)
12 months, n (%)	21 (35.0)	4 (6.7)
Last radiograph, n (%)	10 (22.2)	7 (15.6)

BSIJ, bone:shoulder implant junction score; RLBC, radiolucent line score: extracortical bone and implant collar.

was seen between the bone shoulder and TM collar, however this did not lead to symptomatic aseptic loosening or other associated complications.

Stanmore Radiological Assessment System

The analysis carried out was based on the SRAS,[21] but differed slightly. The RLBC measurement was altered to create a streamlined and efficient assessment that demonstrated a high interobserver reliability. To further reduce the risk of measurement error, the second amendment was made when measuring the BSIJ. The rationale for this approach is that the size of the radiolucent line does not correlate with the outcome measured, namely whether bone growth between the two components had occurred. Furthermore, this approach improves the interobserver reliability as it removes confounding variables such as measurement error. Once again, the statistically significant high kappa values for interobserver reliability are representative of this.

Stem radiolucency cannot occur without radiolucency at the bone:implant junction. It was noted that RLBC occurred in 35% of cases at 12 months; however, at this timepoint, only 3.3% of patients had gone onto develop radiolucency along the length of the stem. At last radiograph, however, RLBC was present in 22.2% of cases but radiolucency along the stem was seen in 17.8% of patients. This shows that stem radiolucency

Table VI. Number of zones that underwent osseointegration.

Period	0 Zones	1 Zone	2 Zones	3 Zones	4 Zones
3 months, n (%)	28 (34.6)	15 (18.5)	19 (23.5)	5 (6.2)	14 (17.3)
12 months, n (%)	21 (35.0)	10 (16.7)	13 (21.7)	8 (13.3)	8 (13.3)
Last radiograph, n (%)	16 (35.6)	11 (24.4)	7 (15.6)	6 (13.3)	5 (11.1)

is a late sign and becomes more prevalent as follow-up time increases.

Only 6.7% of patients showed progression at 12 months on the BSIJ. This would suggest that despite 28.4% of cases showing radiolucency at the bone:collar junction at three months, there is a low risk of progression. This in keeping with Zielinkski et al,[24] who showed that despite radiolucency in initial radiographs of uncemented acetabular components, these radiolucent lines did not progress and regressed in some instances. Two of the four patients showing progression at 12 months went on to show further progression at last imaging – both patients showed extensive radiolucency along the implant stem. Furthermore, of the seven patients who showed BSIJ at last radiograph, five of these had developed radiolucency along the stem. Therefore, it could be hypothesized that BSIJ at last radiograph is associated with stem radiolucency.

Osseointegration

In this study, a TM collar was considered osseointegrated when there was no radiolucent line between the bone and implant, and there was growth of bone level or beyond the corner of the implant. This was consistent with Coathup et al,[21] with regard to defining bony ingrowth. The patients examined in this study showed stable properties when at least one zone was shown to be osseointegrated. Therefore, we believe that one or more zones of OI is needed for there to be confidence in the stability of the implant.

OI has been shown to increase longevity and improve the strength of prosthetic implants while decreasing rates of aseptic loosening.[25] The rates of OI in this study are lower when compared with other studies.[21,22] In 2013, Coathup et al[22] radiologically analyzed OI in hydroxyapatite (HA)-coated collars for EPR procedures and found that 70% of patients showed some degree of radiological OI (timepoint between two and five years, not stated by authors), and at ten-year follow-up, OI had slightly dropped to 66%. The findings from that study are largely in keeping with this study where 64.4% of patients showed OI at last radiograph. In addition, Coathup et al[22] found that the mean score of OI at last radiograph was 1.68 (SD 0.18). This is higher than the TM collars, which averaged an OIS of 1.4 at last radiograph. It should also be highlighted that when an average score was taken from radiographs, only the OIS (n = 29) improved to 2.17, a rise of 55%.

In 2014, Coathup et al[21] undertook a retrospective pair-matched study radiologically analyzing HA collars in patients undergoing an EPR for tumour. Overall, 11 patients received a HA collar and 11 did not; nine of the collar patients showed OI, but only one of the non-collared patients showed OI. Their OI rates were approximately 17% higher than our study (64.4% OI at last radiograph); however, their sample size was four times smaller. The results suggest that the HA collar performs better than the TM collar analyzed in this study, but either a HA or TM collar has a significant benefit when compared with no collar.

The data show that the rates of OI at three months broadly reflect that of the last radiograph (65.6% and 64.4%, respectively). When analyzing zones one to four, there is no definite trend to suggest that a certain score of OI is the most common, as all scores fluctuate in either direction within a range of 5.9% to 7.9% from three months to last radiograph. OI in all four zones does decrease steadily between three and 12 months, and the same again from 12 months to last radiograph. A further study with longer average follow-up may display whether this trend continues to decrease, or if it plateaus at a certain timepoint.

Radiological vs histological analysis

Radiological review was not the only analysis carried out by Coathup et al[22] in 2013; they also carried out histological analysis. In all samples where no collar was used for an EPR for tumour, no OI occurred, and a layer of fibrous tissue formed between any extra-cortical bone (bone that has grown over the implant). When a HA collar was used, they found all samples had OI present. In contrast, Bobyn et al[20] histologically analyzed five samples of TM in dog bone and found no OI, despite the use of a porous coated collar. Radiologically, the implants appeared to have undergone OI, but histology showed a fibrous layer of tissue laid between the extracortical bone and porous implant. While fibrous tissue is not the main goal, it does provide a relative degree of strength and stability, and has been shown to reduce stem and cement stress following segmental periprosthetic arthroplasty.[26]

Heterotrophic ossification

Implant stability is not solely dependent on OI. Several radiographs showed no radiological OI, but it was noted that the implant was well-fixed in its original position with evidence of heterotrophic ossification (HO). The precise mechanism of HO formation is not known but it is thought to arise from the many factors also found in peri-implant haematomas.[27] Despite no OI and collar radiolucency, the presence of HO may lead to increased implant stability.

Weaknesses

This retrospective study has no control group, thus the rates of OI cannot be compared to a non-collar group like Coathup et al[21] in 2015. The establishment of a randomized controlled trial, whether it be multi- or single-centre, would provide an opportunity to compare materials (HA and TM), and provide invaluable data about collars and OI. The nature of oncological work and the low numbers enrolled into studies makes this inherently difficult.

There were only two reviewers scoring, and if there was a difference of opinion between the two, the score from the first reviewer was taken. To make the data analysis more robust, a third reviewer would help with differences in scoring or the two reviewers could discuss the cases in question to come to an agreed conclusion. Despite this, the interobserver correlation scores are excellent in a majority of cases and thus are reassuring.

In future studies, it would also be useful to review the different types of EPR used. We have purely looked at radiological changes and not compared anatomical variances: proximal femur versus distal femoral versus proximal tibia.

In conclusion, this study shows OI does occur in TM collars, but at rates lower than that of HA used for the same purpose. OI will occur by three months and will reflect OI at mid- and long-term follow-up; however, over the longer term, the rate of OI per patient will decrease. The SRAS system may not be the optimum method for assessing OI in TM collars and other determinants of OI should be considered to further assess this.

If radiolucency is seen at the bone:collar junction, it is likely that only low numbers will show progression at longer-term follow-up, and in the absence of infection, radiolucency does not necessarily require revision surgery. Overall, OI does occur with TM collars in EPRs for tumour and more work should be done to investigate the longer-term outcomes.

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Author information

E. Fraser, MBChB, MRCS, Trauma and Orthopaedic Surgical Trainee,
Ninewells Hospital, Dundee, UK.

S. Spence, MBChB, FRCS(T&O), Trauma and Orthopaedic Consultant, Royal Alexandra Hospital, Paisley, Scotland.

O. M. Farhan-Alanie, MBChB, FRCS(T&O), Trauma and Orthopaedic Consultant, The Royal Orthopaedic Hospital NHS Foundation Trust, Birmingham, UK.

J. Doonan, PhD, Orthopaedic Research Manager
A. Mahendra, MBChB, FRCS(T&O), Consultant Orthopaedic Surgeon and Musculoskeletal Oncologist

S. Gupta, MBBS, FRCS(T&O), Consultant Orthopaedic Surgeon and Musculoskeletal Oncologist
Glasgow Royal Infirmary, Glasgow, UK.

Author contributions

E. Fraser: Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review & editing.
S. Spence: Data curation, Methodology, Writing – review & editing.
O. M. Farhan-Alanie: Data curation, Writing – review & editing.
J. Doonan: Data curation, Investigation, Methodology, Writing – review & editing.
A. Mahendra: Conceptualization, Data curation, Supervision, Writing – review & editing.
S. Gupta: Conceptualization, Formal analysis, Supervision, Writing – review & editing.

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