

■ FOOT AND ANKLE

Metallic hemiarthroplasty for the treatment of end-stage hallux rigidus

MID-TERM IMPLANT SURVIVAL, FUNCTIONAL OUTCOME AND COST ANALYSIS

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Aims

To examine the mid-term outcome and cost utility of the BioPro metallic hemiarthroplasty for the treatment of hallux rigidus.

Patients and Methods

We reviewed 97 consecutive BioPro metallic hemiarthroplasties performed in 80 patients for end-stage hallux rigidus, with a minimum follow-up of five years. There were 19 men and 61 women; their mean age was 55 years (22 to 74). No patient was lost to follow-up.

Results

A total of 12 patients (15 first metatarso-phalangeal joints (MTPJs)) required a revision; one for infection, two for osteolysis and 12 for pain. The all cause rate of survival at five years was 85.6% (95% confidence interval (CI) 83.5 to 87.9). Younger age was a significant predictor of revision (odds ratio 1.09, 95% CI 1.02 to 1.17, $p = 0.014$) on excluding infection and adjusting for confounding variables (Cox regression). Significant improvements were demonstrated at five years in the Manchester Oxford Foot Questionnaire (13.9, 95% CI 10.5 to 17.2) and in the physical component of the Short Form-12 score (6.5, 95% CI 4.1 to 8.9). The overall rate of satisfaction was 75%. The cost per quality adjusted life year at five years, accounting for a 14% rate of revision was between £4431 and £6361 depending on the complexity and morbidity of the patient.

Conclusion

The BioPro hemiarthroplasty offers good short to mid-term functional outcome and is a cost effective intervention. The relatively high revision rate is associated with younger age and perhaps the use of this implant should be limited to older patients.

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The presentation of patients with hallux rigidus (HR) with pain, loss of movement primarily in dorsiflexion, and osteophyte formation was described by Cotterill¹ over 100 years ago. This condition is thought to affect one in 45 of the population aged > 60 years, and is more common in females. There are many aetiological factors, but trauma is frequently cited especially in patients with unilateral HR.² Arthrodesis of the metatarsophalangeal joint (MTPJ) remains the benchmark for end-stage HR, with good functional outcomes³ and rates of union of between 90% and 100% have been reported.^{3,4} An arthrodesis limits a patient's ability to kneel and squat, restricts their use of a shoe with a heel, and predisposes them to osteoarthritis of the interphalangeal joint.^{5,6} This has led to the development of arthroplasty for the first MTPJ to preserve the range of movement (ROM), with the benefit of pain relief.

Early silicone implants had high rates of satisfaction,⁷ however with longer follow-up the increased rate of wear, osteolysis and foreign body reactions limited their survival.⁸ Total joint replacements have also been described with good clinical outcome in the short-term,⁹ but mid-term survival data are poor with high rates of osteolysis on radiographic assessment.¹⁰ There is now a growing body of evidence supporting good functional outcome and survival when using hemiarthroplasty of the proximal phalanx for the management of end-stage HR. Townley and Taranow¹¹ designed the BioPro metallic hemiarthroplasty over 60 years ago and reported good to excellent clinical outcomes. Independent authors have supported this and reported good functional outcomes in the short-term.^{12,13} Reports of the survival of this implant vary from 96% at three years¹⁴ to 76% at six years,¹⁵ but these were in relatively small cohorts of < 50

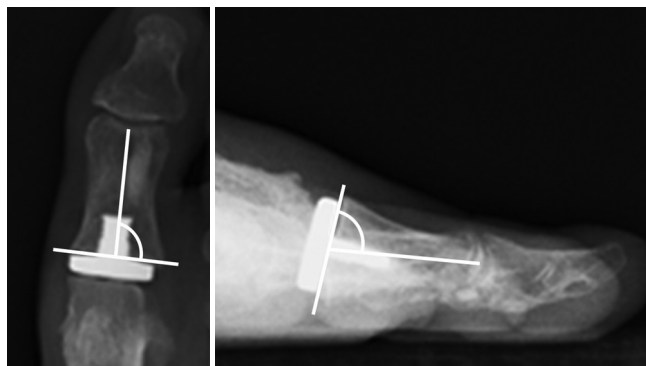


Fig. 1a

Fig. 1b

Radiographic measurement of varus/valgus (a) and extension/flexion (b) of the implant relative to the anatomical axis of the proximal phalanx.

patients. The identification of factors affecting its survival would allow the understanding of which patients would benefit most.

Quality adjusted life years (QALYs) may be used to assess outcome objectively. Measuring the change in health-related quality of life (HRQoL) after an intervention may also be used in conjunction with its cost to calculate a cost-utility ratio i.e. cost per QALYs gained. The National Institute of Clinical Excellence (NICE) use QALYs as the principle measure of health outcome, and recommend interventions accordingly.¹⁶ NICE has not identified specific costs per QALY by which an intervention is or is not recommended. However, in general, interventions with a cost of < £20 000 per QALY gained are considered to be cost effective.¹⁷ In the current cost-saving environment of the NHS, the use of the BioPro would be supported if it was shown to be cost effective.

The primary aim of this study was to describe the mid-term (five to ten years) survivorship and independent pre-operative predictors for survival of the BioPro hemiarthroplasty in patients with HR. Our secondary aims were to assess the functional outcome and patient satisfaction and perform a cost analysis for the procedure according to national tariffs.

Patients and Methods

A total of 97 consecutive BioPro (Biopro Inc., Port Huron, Michigan) metallic hemiarthroplasty implants were used in 80 patients for the treatment of end-stage HR between 2008 and 2010. The patients were retrospectively identified from a prospectively compiled database. There were 19 men (24 MTPJ) and 61 women (73 MTPJ) with a mean age of 54.4 years (standard deviation (SD) 11.2) and 55.7 years (SD 9.7), respectively ($p = 0.59$, t -test).

The surgery was performed or supervised by one of two consultant surgeons (HSS, JMK). All procedures were done as a day case. The first MTPJ was exposed via a dorsal incision medial to the extensor hallucis longus tendon, with a longitudinal capsulotomy. The remainder of the procedure was performed as described by Taranow and Townley.¹⁸ A

standardised rehabilitation protocol was used with immediately bearing full weight in a surgical shoe. The patients were reviewed at ten days and at one and five years. At the ten-day review, they were encouraged to dispense with the surgical shoe and commence exercises of the first MTPJ.

Two end-points were defined for the assessment of survival: all cause revision and aseptic revision (to enable predictors of survival to be identified for reasons other than deep infection). The indication for revision was obtained retrospectively from the patients' notes. Mortality data were obtained from the hospital records and the Scottish Office (Communities Analytical Services, Scottish Executive Justice and Communities) to enable survival analysis to be adjusted for those patients who died during the study period.

Radiographic analysis. The pre-operative radiographs were assessed for the severity (GFD, NDC) of the OA graded from 0 (least affected) to 3 (most affected) using the radiographic atlas defined by Menz et al,¹⁹ which has a high level of reliability. The position of the implant was assessed (Fig. 1) and the hallux valgus angle was measured on post-operative standing radiographs (Kodak Picture Archiving Communication System (Kodak, Rochester, New York) on a liquid crystal display, using tools tab). Patients did not routinely undergo radiographic assessment at mid-term follow-up if they were symptom free. The radiographs performed more than five years post-operatively were assessed for osteolysis, being defined as progressive bone loss with > 2 mm of lucency around the implant or subsidence.

Functional outcome and satisfaction. Patients completed a Manchester Oxford Foot Questionnaire (MOFQ)^{20,21} and a Short Form (SF)-12 score²² pre-operatively, and at one and five years post-operatively, at which time they were also asked to record their level of satisfaction with their toe (for each side if bilateral).

The MOFQ is a validated 16-item, patient-reported outcome measure for evaluating outcomes of foot or ankle surgery.^{20,21} Scores are categorised into three subscales representing: walking/standing problems (seven items), foot pain (five items), and issues related to social interaction (four items). A raw score is then converted to a metric from 0 to 100, where 100 denotes the most severe. The three domain scales have excellent reliability, validity and responsiveness.^{21,22} The minimal clinically important difference (MCID), being the smallest change of a score thought to be of importance, has been defined as a change of 13 points.²³

The SF-12 score²² was used to assess generic general health. It contains 12 items selected from the SF-36 on the basis of their performance across eight dimensions of health. These items are scored to produce two assessments; the physical component summary (PCS) and the mental component summary (MCS). In this case, each of these summary scores can range from 0 representing the worst possible score (most symptomatic) to 100 being the best possible score (least symptomatic). The MCID was defined



Fig.2

Anteroposterior radiograph of a 50-year-old male who underwent revision for bilateral osteolysis of the proximal phalanx at 3.2 and 3.7 years. There was minimal cortical bone loss and arthrodesis was undertaken.

as half the standard deviation of the pre-operative SF-12 score (6 points), which is an accepted methodology.^{24,25}

Satisfaction was assessed by the question "How satisfied are you with your operated toe?". The response was recorded using a four point Likert scale: very satisfied, satisfied, neutral and dissatisfied. Patients were then categorised into those that were satisfied (very satisfied and satisfied) and those who were not (neutral and dissatisfied), which has been used previously to assess satisfaction after knee replacement.²⁶ We also asked those who had not undergone a revision at the last follow-up "how satisfied are you with the range of motion in your toe?". The response was recorded using a five point Likert scale: very satisfied, satisfied, neutral, dissatisfied and very dissatisfied.

Cost analysis. A single preference based index measure (SF12-6 dimension (D)) was also calculated, which is required to calculate a QALY. This calculation was made as described by Brazier and Roberts;²⁷ by using seven components of the SF-12 score, a single preference based index measure can be assigned to each patient. The SF12-6D evaluates six domains including physical functioning, role limitations, social functioning, pain, mental health and vitality. This index is measured on a scale of 0 to 1, where 1 represents perfect health and 0 represents death. The health state gained from the BioPro, derived as the difference between the pre-operative and the most recent SF12-6D, which was then multiplied by the number of years spent in that state to derive the QALYs gained or lost.

The benefit from the BioPro would potentially continue throughout the predicted life expectancy of the patient, and the implant. However, as there are no long-term data to support survival beyond that reported in this study of five years, we have chosen to use this time point to calculate the cost per QALY. This will reflect the true cost of the implant at the mid-term accounting for revision. The cost of surgery was obtained from the English National Tariff, being

defined as an intermediate day case procedure for patients aged > 19 years. The costs have been found to range from £1688 for patients with no comorbidities, to £2556 for complex patients with comorbidity.²⁸ Costs per QALY were calculated for best (least expensive) and worst (most expensive) case scenarios. The cost of revision was taken as a mean of the intermediate procedures (£2122).

Ethical approval was obtained from the regional ethics committee (Research Ethics Committee, South East Scotland Research Ethics Service, Scotland, 11/AL/0079) for collection, analysis and publication of the data contained within the study. All patients gave their written consent to participate in this research.

Statistical analysis. Statistical Package for Social Sciences version 17.0 (SPSS Inc., Chicago, Illinois) was used to analyse the data. Both a paired and unpaired Student's *t*-test was used to compare linear variables between groups. Pearson's correlation was used to assess the relationship between linear variables. Dichotomous variables were assessed using a chi-squared test. Kaplan-Meier methodology²⁹ and a life table were used to investigate implant survival.³⁰ Cox regression analysis was used to identify independent predictors of survival of the implant. A *p*-value of < 0.05 determined statistical significance.

Results

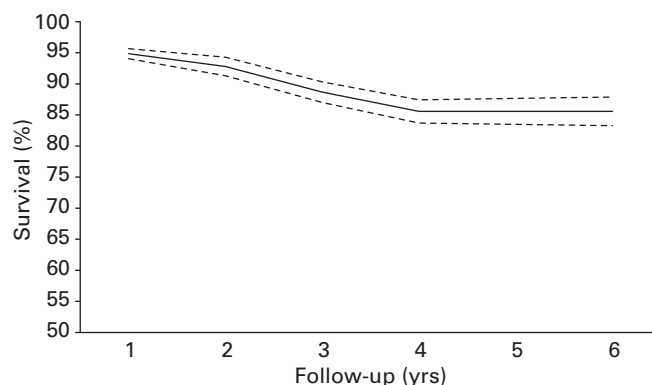
The osteoarthritis was grade 2 for 16 first MTPJs and grade 3 for the remaining 81. No patient was lost to follow-up; however, one patient died during the study period (4.7 years post-surgery). The median follow-up for all patients, including those who were deceased or had been revised (taken as time of revision), was 5.4 years (4.7 to 8.2).

Survival. A total of 12 patients underwent 15 revisions, of which one was for deep infection, two for osteolysis and 12 for persistent pain. The patient with the deep infection had an excision arthroplasty at 18 months with a prolonged course of antibiotics (six weeks) and remained free of infection six years post-operatively. The two cases of osteolysis were seen bilaterally in the same patient; a very active 50-year-old man who played tennis regularly and did not want an arthrodesis primarily. Bilateral arthrodeses were subsequently undertaken at 3.2 and 3.7 years post-operatively. The remaining ten patients (12 MTPJs) were revised for pain; six underwent an arthrodesis and six an excision arthroplasty. One of these patients presented six years following surgery with pain after a fall three months previously. There was fixed hyperextension of the first MTPJ and erosion of the neck of the first metatarsal. These changes were thought to be due to dislocation of the joint following trauma. Revision to an arthrodesis was undertaken.

The decision to convert to arthrodesis (*n* = 8) or excision arthroplasty (*n* = 7) was based on the patient's expectations, with the exception of the deep infection where an excision arthroplasty was performed. Patients who wanted to retain mobility at the joint underwent an excision arthroplasty, whereas higher demand patients had an arthrodesis

Table I. Life table for survival of the BioPro metallic hemiarthroplasty

Yrs since operation	Number at start	Failure	Withdrawn	Number at risk	Annual failure rate (%)	Cumulative survival	95% confidence interval	
							Lower	Upper
0 to 1	97	5	0	97	94.8	94.8	94.0	95.7
1 to 2	92	2	0	92	97.8	92.8	91.3	94.3
2 to 3	90	4	0	90	95.6	88.7	87.0	90.3
3 to 4	86	3	0	86	96.5	85.6	83.7	87.4
4 to 5	83	0	24	71	100.0	85.6	83.5	87.7
5 to 6	59	0	47	35.5	100.0	85.6	83.3	87.9

**Fig. 3**

Kaplan Meier curve, with 95% confidence intervals (dashed lines) for all cause survival of the BioPro metallic hemiarthroplasty implant (n = 97).

Table II. Comparison of pre-operative and five year patient-reported outcome measures (PROMs) for all joints (n = 81)

PROMs	Score			95% confidence interval		p-value*
	Pre-operative	Post-operative	Difference	Lower	Upper	
PCS12	36.7 (11.8)	44.2 (13.4)	7.6	4.8	10.3	< 0.001
MCS12	50.8 (11.0)	51.3 (9.0)	0.5	-1.2	2.3	0.55
MOFQ	53.2 (16.5)	33.2 (16.1)	20.0	16.4	23.6	< 0.001

* paired t-test

PCS, physical component summary; MCS, mental component summary; MOFQ, Manchester Oxford Foot Questionnaire

with acceptable shortening of the first ray. Bone loss was not a significant determining factor at revision in any of the 15 first MTPJs, and hence for the patients undergoing arthrodesis no bone graft or substitute was required. An example of the limited cortical bone loss is illustrated in Figure 2, despite balloon osteolysis in the proximal phalanx there remains adequate cortical bone to perform an arthrodesis with acceptable shortening of the ray.

The all cause rate of survival for the BioPro implant at five years was 85.6% (95% confidence interval (CI) 83.3 to 87.9) (Table I). The all cause rate of survival was generally consistent from three years and more, with 14 revisions in 11 patients being performed within four years of the initial surgery (Fig. 3). The aseptic rate of survival was 86.5% (95% CI 85.2 to 87.8). Gender ($p = 0.61$), radiographic severity of the osteoarthritis ($p = 0.85$), pre-operative SF-12 PCS ($p = 0.75$), MCS ($p = 0.51$) and MOFQ ($p = 0.75$)

scores, radiographic measures of the position of the implant (varus/valgus $p = 0.10$, flexion/extension $p = 0.49$) and hallux valgus angle ($p = 0.28$) were not significant predictors of aseptic revision of the BioPro implant (Cox regression analysis). However, younger age was a significant independent predictor of aseptic revision (odds ratio 1.09; for each decreasing year; 95% CI 1.02 to 1.17, $p = 0.014$).

At final follow-up only 23 of the 81 implants that had not been revised had a radiograph performed at a median follow-up of five years (interquartile range 5 to 7). There was no case of osteolysis, but all 23 had a non-progressive lucent line (< 2 mm) on the lateral radiograph between the dorsal aspect of the implant and proximal phalanx.

Functional outcome and satisfaction. Functional data were available for 81 of the 82 joints not revised at final follow-up. There was a significant improvement in the MOFQ and the SF-12 PCS score (Table II), which were both beyond the

Table III. Comparison of pre-operative and five year patient reported outcome measures (PROMs) for patients that underwent revision (n = 14)

PROMs	Score		Difference	95% confidence interval		p-value*
	Pre-operative	Post-operative		Lower	Upper	
PCS12	38.9 (11.6)	39.1 (11.1)	0.2	-1.6	2.1	0.78
MCS12	52.9 (9.0)	50.0 (8.9)	2.9	-3.9	9.7	0.37
MOFQ	48.4 (17.1)	42.9 (18.8)	5.6	0.2	11.0	0.04

* paired t-test

PCS, physical component summary; MCS, mental component summary; MOFQ, Manchester Oxford Foot Questionnaire

Table IV. Health economic analysis using the improvement in the Short Form (SF)12-6D health evaluation score five years post-operatively for BioPro hemiarthroplasty (n = 97). Demonstrating the costs for the best (simple patient with no comorbidities) and worst (complex patient with comorbidities) case scenarios

Health economic analysis	Best case	Worst case
SF12-6D (n = 78 joints)		
Pre-operative (mean, SD)	0.686 (0.159)	0.686 (0.159)
Post-operative (mean, SD)	0.777 (0.151)	0.777 (0.151)
Difference (mean, 95% CI)	0.090 (0.054 to 0.125)	0.090 (0.054 to 0.125)
Procedural cost	£1688	£2556
Overall cost (n = 97 joints)	£163 736	£247 932
Revision cost	£2122	£2122
One year (n = 5 revisions)	£10 610	£10 610
5 years (n = 14 revisions)	£29 708	£29 708
Outcome 1		
Total cost	£174 346	£258 542
One year cost per QALY (95% CI)	£19 970 (£14 379 to £33 284)	£29 615 (£21 323 to £49 359)
Outcome 2 (86% survival)		
Total cost	£193 444	£277 640
5-year cost per QALY (95% CI)	£4431 (£3190 to £7386)	£6361 (£4580 to £10 600)

SD, standard deviation; SF, short form; CI, confidence interval; QALY, quality adjusted life years

MCID. There was no significant change in the MCS score of the SF-12 ($p = 0.55$, t -test). A total of 61 joints (75%) had a satisfactory outcome. Satisfaction with ROM was however significantly greater with 73 joints (90%) having a satisfactory outcome (OR 2.8, 95% CI 1.2 to 6.5, $p = 0.002$).

Functional data were available for 14 of the 15 joints that were revised at final follow-up. There was a significant improvement in the MOFQ score (Table III), but this was not beyond the MCID. There was no significant change in the mean SF-12 PCS or MCS scores (Table III). Nine patients (64%) declared they were satisfied with the outcome, which was not significantly different to those patients who did not undergo revision surgery ($p = 0.34$, chi-squared test).

Cost analysis. There were SF12-6D data available for 78 joints of the 82 with a minimum of five years follow-up who had not undergone revision. The mean pre-operative SF12-6D score was 0.686 (SD 0.159), which increased to 0.777 (SD 0.151) at a mean follow-up of 5.4 years. There was a 0.090 (95% CI 0.054 to 0.125) QALY gain which was statistically significant ($p < 0.001$, t -test). The gain in

QALYs observed at five years was then used to calculate the cost per QALY at this time for the study cohort. Using the revision rate observed for the study of 14% at five years, the adjusted cost per QALY was found to be £4431 for the best and £6361 for the worst case scenario (Table IV).

Discussion

We found an 85.6% mid-term survival rate for the BioPro hemiarthroplasty when used for the management of end-stage HR. Younger age was a significant independent predictor of failure when adjusting for confounding variables. There was a significant improvement in the localised symptoms (MOFQ) and the overall general health (SF-12 PCS) of those who did not undergo revision, which was beyond the MCID. Interestingly, even patients who underwent a revision also had a significant improvement in their symptoms (MOFQ). Despite this improvement only 75% ($n = 61/81$) of joints had a satisfactory outcome at five years. The overall cost per QALY at five years when adjusting for revision ranged from £4431 to £6361 depending on patient comorbidities, making it a cost-effective intervention.

Despite nine published studies, of which we are aware,^{11-15,31-34} only five^{11,13,14,33,34} report a rate of survival for the implant and only one¹⁵ used Kaplan-Meier methodology to adjust for the time-dependant nature of follow-up. The 85.6% implant survival rate in our patients is supported by other authors reporting early results of the BioPro implant. Simons et al¹⁴ recently reported a rate of survival of 96% at three years for 46 patients, whereas Giza et al³⁴ reported a rate of 91% at two years for their cohort of 22 patients. Raikin and Ahmad¹⁵ reported a 76% rate of survival at six years for a cohort of 21 patients, who were treated with the BioPro implant as part of a randomised controlled trial. They also observed a similar pattern of survival, with most failures occurring in the first two to three years. However, longer-term studies would be needed to confirm that the mid-term rate of survival remains static. An original aspect of our study was to identify younger age as an independent predictor of failure after adjusting for confounding variables. For example, a patient who is 40 years old has twice the risk of failure than a patient who is 50 years old. Hence, it would seem the BioPro should be restricted to older patients. However, it is not clear what this cut-off age should be, and it is probably also related to the activity level of the patient.

This study has confirmed a significant improvement in early symptoms (MOFQ) and that this improvement is observed into the mid-term. Many authors have also reported significant improvement in the region-specific patient reported questionnaires, but this was for one to three years follow-up.^{13,14,34} We also found a significant improvement in generalised physical health status (SF-12 PCS), which is a new finding. This may be related to an improvement in the activity level with pain relief offered by the hemiarthroplasty. However, despite this improvement, there was also a low rate of satisfaction of 75%. This low rate may be explained by the longer follow-up of our study, but may also be due to the definition of satisfaction used.²⁶ We classified a patient dissatisfied if they declared their outcome as neutral or dissatisfied as this had previously be used. If only those patients declaring their outcome as dissatisfied (n = 10) were used, the overall rate of those satisfied would increase to 88%.

The cost-utility analysis showed that the cost per QALY at five years for this implant was between £4431 and £6361 depending on the complexity and morbidity of the patient, which is a new finding. Total hip arthroplasty (THA) is regarded by some to be one of the most cost effective operations in orthopaedics.³⁵ Jenkins et al³⁶ reported the cost per QALY to be £1372 for THA after adjusting for revision costs to the end of life. Dakin et al³⁷ reported a cost per QALY for total knee arthroplasty (TKA) of £5623 five years post-operatively. Hence, it would seem that the BioPro implant may not offer the same value for money as THA, but is similar to the cost effectiveness of a TKA. However, with all these procedures the cost per QALY is far below the threshold value of £20 000 to £30 000, above

which NICE are reluctant to recommend drugs or treatments.¹⁷

The retrospective design of this study is a major limitation. No patient was, however, lost to follow-up, outcome scores were available for more than 95% of the patients (81/82 joints not revised). The limited radiographic assessment of the patients at mid-term follow-up is also a limitation, although there were no concerns raised in this study regarding osteolysis or migration of the implant for those reviewed at five years. However, further assessment of this implant is needed to assess the survival and functional outcome in the long-term, to confirm our findings and to assess predictors of survival which could be used as indications for use of the BioPro. A further limitation is not measuring the ROM pre- and post-operatively to assess whether this had improved. However, we found that 73 of 81 joints (90%) had a satisfactory range of movement. Previous authors have shown a significant improvement in ROM,^{13,34} but whether this correlates with function remains unknown. However, we assessed function and subjective outcome which are probably the most important elements of judging success in joint replacement surgery.³⁸

The BioPro offers good short- to mid-term functional outcome and is a cost-effective intervention. The relatively high revision rate is associated with younger age and perhaps the use of this implant should be limited to older patients.



Take home message:

The BioPro offers good mid-term survivorship and functional outcome for the treatment of end stage HR.

Author contributions:

N. D. Clement: Data collection, Data analysis, Performed surgeries, Writing the paper, Paper submission and revision.

D. MacDonald: Data collection, Data analysis.

G. F. Dall: Data collection, Data analysis, Writing the paper.

I. Ahmed: Data collection, Data analysis.

A. D. Duckworth: Data analysis, Preparation of manuscript.

H. S. Shalaby: Data collection, Data analysis, Performed surgeries, Writing the paper, Paper submission and revision.

J. McKinley: Data collection, Data analysis, Performed surgeries, Writing the paper, Paper submission and revision.

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