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ORIGINAL ARTICLE

# Bioring® gastric banding for obesity in a private South African hospital

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**Background:** Obesity is a significant health problem in South Africa. Surgery is the most effective means of durable weight loss for the morbidly obese. Of the surgical options, laparoscopic adjustable gastric banding is the most controversial. We aimed to assess a single surgeon's experience with a specific band.
**Methods:** A retrospective observational study of a continuous cohort of laparoscopic adjustable gastric Cousin Bioring® band placements from a single private South African hospital was conducted. Three hundred and fifty bands were placed in 347 patients, 75% were female. Variables analysed were BMI obesity class, comorbidities, weight loss, diabetes resolution, adherence to aftercare, patient satisfaction, complications and death.
**Results:** Outcomes were assessed in 343 patients (4 patients lost to follow-up). The mean follow-up was 39 months (IQR 29–66 months). The mean preoperative BMI was 43.3 kg/m² (IQR 37.4–47.6 kg/m²). Most weight loss occurred in the first year, and 66% achieved > 40% excess weight loss. Resolution of type 2 diabetes and prediabetes occurred in 56.4% and 89.8% of patients respectively. Increasing age ($p = 0.002$), class 3 obesity ($p < 0.001$) and suboptimal aftercare ($p < 0.001$) were associated with failure. One patient developed band erosion and 40 developed band slippage, 34 of whom underwent secondary surgery (32 removals, 2 revisions). All complications were grade I–III. There was no high grade complication, and no death.
**Conclusions:** Bioring® gastric banding achieved moderately good weight loss and resolution of type 2 diabetes with a low complication rate. BMI > 60 and suboptimal aftercare predicted poor outcome.
**Keywords:** gastric banding, South Africa

## Introduction

Obesity poses a health challenge and South Africa is experiencing an epidemic across its ethnic spectrum.[1,2] A 2013 analysis reported 42% of South African adult females as obese, and close to 70% as either overweight (BMI 25–30 kg/m²) or obese (BMI > 30 kg/m²).[3]

Surgery is recognised as the most effective and durable treatment.[4-7] In the context of South Africa's national healthcare policy, weight loss surgery is not deemed a priority in the state sector with tertiary institutions running very limited programmes,[8] and only specific medical aids funding the surgery in the private sector.[9] Although all weight loss procedures are now regarded as safe,[7,10,11] referral for surgery is often tardy because of perceived surgical risk and cost.

In South Africa, bariatric surgery centres of excellence have been established and accredited. These centres favour laparoscopic procedures that create stapled suture lines to construct a restrictive operation, e.g. sleeve gastrectomy (SG) or a restrictive and malabsorption operation, e.g. Roux-en-Y Gastric Bypass (RYGB). In keeping with recent international trends, they do not perform gastric banding. They base this practice on reports of large databases and observational cohorts showing both sustained weight loss and improvement in diabetes, especially with RYGB.[10-13] In contrast, long-term results particularly with the LapBand® procedure in Australia have also demonstrated sustained weight loss with comorbidity resolution and low complication rates.[7,14,15] Band design has also evolved to ease insertion and removal, and to reduce the likelihood of migration and erosion.[16,17]

In this report, mid-term outcomes of a South African single-hospital consecutive series of laparoscopic Bioring® bands are documented. The Bioring® band was chosen because of its ease of insertion and removal, and because it exerts a low pressure even when full.[17] The question was asked as to whether this band might be effective both in terms of weight loss and resolution of diabetes, and whether it has a low complication rate.

## Methods

The records of patients from a database of all patients scheduled for laparoscopic Bioring® banding between January 2011 and July 2018 at Life Glynnwood Hospital were reviewed. Alternative weight loss interventions were not offered during this period.

### *Patient selection and preoperative assessment*

Patients were required to be obese with a BMI 30–40 kg/m² with one or more comorbidities or a BMI > 40 kg/m² with or without comorbidities. Patients were

categorised by obesity class.[18-20,7] Patients who had undergone previous hiatal hernia repair were excluded. Preoperative evaluation included screening on history for diabetes, dyslipidaemia, arthritis, hypertension, coronary artery disease and depression, polycystic ovary syndrome and medicinal usage. Diabetes and prediabetes were diagnosed on the basis of $HbA_1C$ levels. Serum lipid profiling and renal and liver function testing were performed selectively. Fatty liver and asymptomatic gallstones were diagnosed on ultrasound and liver function tests. Sleep apnoea was diagnosed based on continuous positive airway pressure machine usage or prior sleep laboratory referral. Preoperative nutritional assessment was made by dietician who also oversaw post-procedural nutritional advice. Patients with gastroesophageal reflux symptoms underwent evaluation to exclude a large hiatus hernia. After initial workup was complete, the surgeon conducted informed consent counselling which included a comprehensive procedure video.

### *Technique*

All patients followed a preoperative fatty liver shrinkage diet.[21] They received combined mechanical and pharmacological venous thromboembolism prophylaxis[22] and a 2 g dose of prophylactic cefazolin. Bioring® bands were placed above the posterior omental sac by the pars flaccida route[23] using 4 ports, a Nathanson® liver retractor, and an articulated band pull through instrument. Pouch size was estimated visually and made as small as possible. Band size (10 ml, 15 ml or 20 ml) was also judged visually so as to be snug, but not tight. Three non-absorbable gastro-gastric sutures were interspaced between the greater and lesser stomach curvatures to prevent anterior slippage.

### *Aftercare*

First band fills were made one month after surgery. Initial fill volumes were made according to the patient's band size (3 ml for 10 ml band, 4 ml for 15 ml band, and 5 ml for 20 ml band). Aftercare visits every three months during the first postoperative year, and every six months thereafter were emphasised as being mandatory. Reminder emails and text messages were used to minimise aftercare defaults. Subsequent volume adjustments were based on weight loss progress and consideration of side effects. Neither fluoroscopy nor band manometry was used to guide fill volumes.[24,25] The dietician emphasised that patients should eat slowly, as their band aimed to produce early satiety to reduce energy intake, without inducing symptoms of obstruction.[26,27]

## Data collection

Data retrieved for all patients included demographic details, comorbidities, and medicinal usage. Early (within a month) and late complications were noted. Complications were graded according to Dindo Demartines Clavien Grading.[28] Operative mortality was defined as death precipitated by surgery and occurring within thirty days of surgery. Follow-up information was obtained from three months prior to the closure of patient accrual to nine months after closure. All information was obtained by the lead author, either face to face, telephonically, or by email. At last contact, weight, wellbeing, satisfaction evaluation, and number of months elapsed since insertion were recorded. The primary endpoint was achievement of > 40% excess weight loss (EWL). The secondary endpoint was the resolution or amelioration of prediabetes/diabetes. Prediabetes resolution meant reversion of HbA1C level[29] to normal, and diabetes resolution cessation of anti-diabetic medication/s.[30,31] Inadequate aftercare was defined as fewer than three visits within the first year, and incomplete aftercare as no visit/s beyond the first year. Aftercare was labelled as suboptimal if it was either inadequate or incomplete. Lost to follow-up was defined as uncontactable at the conclusion of the study period. Patients resident outside of South Africa or more than 400 km away were entered as geographically remote.

### *Statistical analysis*

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 24 (IBM, USA). Means were compared using the t-test for equality of means, both in paired and independent samples. Pearson's $\chi^2$ test was used to compare categorical variables. If the projected frequency, assuming a true null hypothesis, in a cell of a two-by-two table was less than five observations, we used Fisher's exact test. Multiple univariate logistic regressions were used to determine the odds ratios for failure. A $p$-value $< 0.05$ (5%) was considered statistically significant.

## Results

In 347 of 348 consecutive patients, 350 Bioring® bands were placed. Band placement was not achieved in one patient (a male with prohibitive hepatomegaly and BMI 75.1 kg/m$^2$) and 3 patients received a second band. Of the 348 patients, 262 (75.3%) were female and 86 (24.7%) were male. The mean age was 40.6 years (SD ± 10.6; IQR 33–48 years). The mean BMI at entry was 43.3 kg/m$^2$ (IQR 37.4–47.6 kg/m$^2$). The mean starting weight was 123.0 kg (IQR 103.0–138.4 kg). The breakdown of patients by obesity class and comorbidity is detailed in Table I.

### *Previous procedures and synchronous procedures*

Four patients had bands placed several months after reversal of a previous open jejunoileal bypass operation. One patient had undergone an open and a laparoscopic cholecystectomy. Synchronous procedures were performed in 39 patients: an umbilical hernia repair, a cholecystectomy and 36 posterior diaphragmatic crural plications for small hiatal hernias.

### *Aftercare attendance and end of study follow-up*

The mean duration since surgery was 39.1 months (IQR 29–66 months). End of study follow-up (158 face-to-face, 39 email, 126 telephonic, and 20 text message) was achieved in 343 of the 348 patients (98.5%). Four patients failed to both adequately attend during their first postoperative year and were lost to follow-up. Aftercare attendance was inadequate in 38 patients (11.1%) and incomplete in 17 patients (5.0%). Of the 55 (16.1%) with suboptimal aftercare, 23 (41.8%) were geographically remote. This association was significant ($p = 0.018$).

### *Outcomes*

The primary endpoint of > 40% EWL was achieved in 228 (66.3%) patients. Patients' weight loss progress is represented in Figure 1. There -was no significant difference in

**Table I: Obesity categories and comorbidities**

| Comorbidity | Obesity category | | | | | | | | | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Class 1 ($n$ = 40) | | Class 2 ($n$ = 95) | | Class 3 ($n$ = 213) | | | | | | ($n$ = 348) | |
| | BMI 30–34.9 kg/m² | | BMI 35–39.9 kg/m² | | BMI 40–49.9 kg/m² | | BMI 50–59.9 kg/m²* | | BMI ≥ 60 kg/m²** | | | |
| | *N* | % | *N* | % | *N* | % | *N* | % | *N* | % | *N* | % |
| Prediabetes[1] | 8 | 20 | 15 | 16 | 15 | 10 | 5 | 9 | 1 | 8 | 49 | 14.1 |
| Diabetes | 13 | 32 | 14 | 15 | 31 | 21 | 18 | 33 | 2 | 17 | 78 | 22.4 |
| NAFLD[2] | 4 | 10 | 9 | 9 | 17 | 12 | 5 | 9 | 3 | 25 | 38 | 10.9 |
| Dyslipidaemia | 8 | 20 | 18 | 19 | 36 | 25 | 20 | 36 | 5 | 42 | 87 | 25 |
| Coronary artery disease | 7 | 17 | 16 | 17 | 28 | 19 | 16 | 29 | 4 | 33 | 71 | 20.4 |
| Hypertension | 8 | 20 | 16 | 17 | 48 | 33 | 23 | 42 | 8 | 67 | 103 | 29.6 |
| Arthritis | 4 | 10 | 15 | 16 | 28 | 19 | 15 | 27 | 4 | 33 | 66 | 19 |
| Depression | 7 | 17 | 18 | 19 | 21 | 14 | 8 | 15 | 3 | 25 | 57 | 16.4 |
| Gastro-oesophageal reflux | 10 | 25 | 21 | 22 | 39 | 27 | 17 | 31 | 5 | 42 | 92 | 26.4 |
| Obstructive sleep apnoea[3] | 1 | 2 | 4 | 4 | 10 | 7 | 8 | 14 | 2 | 17 | 25 | 7.2 |
| Polycystic ovarian syndrome | 3 | 7 | 4 | 4 | 5 | 3 | 3 | 5 | 0 | 0 | 15 | 4.3 |
| Gestational diabetes[4] | 1 | 2 | 2 | 2 | 1 | 1 | 2 | 4 | 2 | 17 | 8 | 3.1 |

*Super-obese, **Super-super-obese
[1]HbA1C levels 5.7–6.4%, [2] on liver function tests or ultrasound, [3]using CPAP machine, [4]history of

mean weight loss at 1 year compared to the entire follow-up period ($p = 0.150$).

Prediabetes resolved in 44 of 49 patients (90%) and diabetes in 44 of 78 patients (56%). One patient, whose diabetes resolved at 15 months, relapsed at 65 months. No insulin dependent diabetic was able to discontinue insulin. There was a significant association between achieving successful weight loss and resolution of diabetes ($p < 0.001$).

### *Complications, deaths and secondary surgeries*

There were no operative deaths. Three patients died during the follow-up period. Their deaths were due to H1N1 influenza pneumonia, motor vehicle accident and breast cancer. Postoperative complications are detailed in Table II. No grade IV or V complication occurred.

Band slippage occurred in 40 patients (11.6%) and 32 bands were removed for slippage. Two slipped bands were revised. A single patient developed band erosion and made an uneventful recovery after it was removed laparoscopically. Two infected (skin derived methicillin sensitive Staphylococcus aureus) bands required removal. In total, 37 bands were removed, and secondary surgery was necessary in 44 patients (12.8%). The band explantation rate was 1.5% per annum. The mean time to removal was 32.8 months (range 7–73 months). Three patients (0.87%) had second bands placed several months after having had a first band removed for slippage. Two failure patients underwent band removal with conversion to a different procedure by other surgeons (RYGB and SG respectively). Four patients became pregnant with a band in situ. One suffered a spontaneous abortion at two months of pregnancy. The remaining three patients' pregnancies were uncomplicated. One patient required her band to be deflated for the duration of her pregnancy.

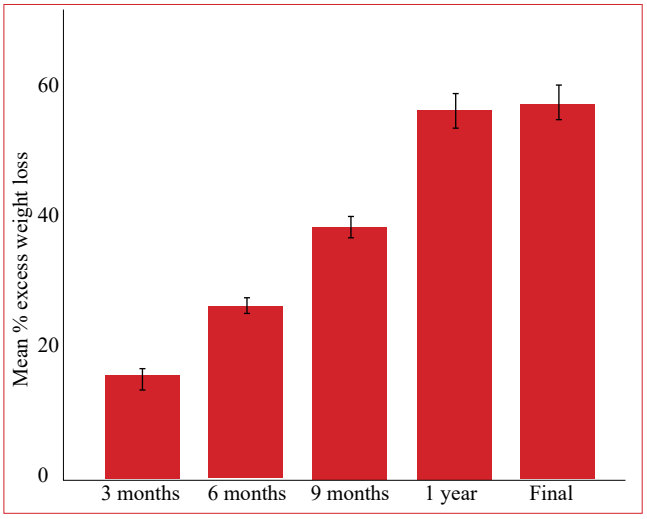


*Figure 1: Weight loss over time*

**Table II: Early and late complications**

| Complication | *N* | % | Grade* |
|---|---|---|---|
| **Early complications (within 1 month)** | **2** | **0.6** | |
| Re-admission for vomiting | 1 | 0.3 | II |
| Deep vein thrombosis | 1 | 0.3 | II |
| **Late complications (after 1 month)** | **90** | **27.7** | |
| Heartburn requiring PPI | 45 | 13.1 | II |
| Band slippage managed by band deflation | 9 | 2.6 | II |
| Heartburn requiring gastroscopy | 13 | 3.8 | IIIa |
| Band slippage requiring revision/removal | 31 | 9.0 | IIIb |
| Sepsis without erosion | 2 | 0.6 | IIIb |
| Sepsis with erosion | 1 | 0.3 | IIIb |
| Port complications (damage, twisting) | 2 | 0.6 | IIIb |

*Dindo Demartines Clavien Severity Grade

| Table III: Reasons for secondary surgeries | | |
|---|---|---|
| **Reason for secondary surgeries** | ***N*** | **%** |
| Band removal | 35 | 83.3 |
| Slippage | 32 | 76.2 |
| Sepsis | 2 | 4.8 |
| Erosion | 1 | 2.3 |
| Band revision for slippage | 2 | 4.8 |
| Metachronous new band insertion | 3 | 7.1 |
| Port replacement (needle stick damage) | 1 | 2.3 |
| Port re-fixation (twisting) | 1 | 2.3 |

| Table IV: Factors associated with failure to achieve > 40% EWL | | |
|---|---|---|
| **Parameter** | **OR (95% CI)** | ***p*-value** |
| Age (years) | 1.04 (1.01–1.06)* | **0.002** |
| Gender | 0.80 (0.48–1.32) | 0.380 |
| Entry BMI ≥ 40 (class 3 obese) | 2.87 (1.74–4.74) | **< 0.001** |
| Entry BMI ≥ 60 (super-super obese) | 3.36 (1.08–10.52) | **0.037** |
| Presence of diabetes | 1.25 (0.74–2.11) | 0.414 |
| Presence of depression | 1.10 (0.61–2.00) | 0.759 |
| Suboptimal aftercare | 30.6 (12.6–74.5) | **< 0.001** |
| Geographically remote | 2.32 (0.99–5.43) | 0.053 |

*Analysed as a continuous variable. Each increase in age by 1 year resulted in a 1.04-fold increase in the risk of failure.
Bold indicates significant finding.

### *Factors associated with outcome*

Factors associated with failure are detailed in Table IV. Of the 348 patients, 116 (33.3%) failed to achieve and 232 (66.7%) achieved > 40% EWL. Mean age was significantly different between failure (mean 43.1; SD ± 10.1 years) and success (mean 39.5; SD ± 10.3 years) groups ($p = 0.002$). Each increase in age by 1 year resulted in a 1.04-fold increase in the likelihood of failure ($p = 0.002$). In addition, class 3 obesity ($p < 0.001$) and poor aftercare ($p < 0.001$) were significantly associated with failure.

## Discussion

This study showed that > 40% EWL was achieved in 67% of Bioring® banded patients. We view this as moderate success. Although band type and duration of follow-up differ between studies, fourteen out of seventeen series[11,14,32-46] identified by O'Brien et al.[15] documented similar success. It also showed that close to 50% of type II diabetics were able to discontinue anti-diabetic medications. This is superior to the 10% reported by Niville et al.,[47] but below the 73% achieved by Dixon et al.[48,49] Not one of 8 insulin dependent diabetics was able to discontinue insulin. As in other series[10,15,30,39,50-56] the procedure proved to be very safe, and complications were infrequent and all low grade.

We operated on 40 (11.5%) class 1 patients, all of whom had at least one comorbidity. Although inclusion of class 1 patients differs from NICE[19] and NIH[20] guidelines, it accords with other published recommendations,[7] and with a prospective trial which compared results of banding versus best medical therapy in class 1 obesity.[50]

Band slippage occurred in 40 patients (11.5%), of which 39 manifested beyond a year. A distinction between pouch overstretch and stomach slippage was not apparent. All patients presenting with food intolerance (regurgitation of all intake) were labelled as having slippage. This is a liberal definition, which to a degree likely explains the high prevalence in this series compared with that of Giet et al. who reported a mere 1.7% slippage rate.[57] Most (34 of 40, 85%) slippage patients in this series came to secondary surgery. Thirty-two slipped bands were removed, and 2 were revised. Revision entailed unlocking the band, removing previous gastro-gastric sutures, pulling down the enlarged pouch, re-locking the band, and new anterior gastro-gastric suturing. Although technically more demanding and less predictable than removal in relieving eating intolerance, we believe that revision should be considered if the patient's general condition is satisfactory. Beitner et al. viewed revision as part and parcel of band maintenance,[56] and Niville et al. were able to revise all their slipped bands without device removal.[47] It is apparent, however, that a foolproof anti-slip method (better than anterior gastro-gastric suturing) would be beneficial. Our band attrition rate was just under 1.5% per annum. It is likely that with longer follow-up[58] numbers will increase.

Band erosion is rare,[59-61] and the rate appears to vary according to band type. We encountered only one patient (1/343, 0.29%). His band eroded at 2 years. This compares with Niville et al. who documented a 1.66% erosion rate in a Lap-Band® series,[61] and with 0.04% in the Bioring® series of Giet et al.[57] An outlier Lap-Band erosion prevalence of 33% was reported by Himpens et al.[37] We attribute our low erosion prevalence to the low pressure exerted on the gastric wall and the bellows-like action on inflation of the Bioring® band.[17]

Increasing age, super-super obese status, and suboptimal aftercare were identified as predictors of failure. Geographic remoteness contributed to suboptimal aftercare but was not an independent predictor of failure. In future, we aim to exclude patients of BMI > 60 kg/m$^2$, patients over 65 years of age, and remote patients. These predictors of failure have not previously been reported. Varban et al.[54], however, did observe that BMI < 40 kg/m$^2$ correlated with greater success in their series.

A decade ago, gastric banding was the worldwide leading weight loss operation.[52] Nowadays, SG holds this position.[62-65] In our opinion, the durability of SG needs further confirmation. To date only 3 SG series have reported results beyond ten years.[62-64] A contributing factor to banding decline is that aftercare has to be intensive and ongoing, and this is a demand on resources. Aftercare is best if it is protocol driven. Non-reporters need to be repeatedly summoned to attend. In our series, suboptimal aftercare was a significant predictor of failure (see Table IV). Also, certain band types (Lap-Band® and Bioring®) likely have fewer complications than others. Despite these considerations, it remains difficult to explain today's divergent opinions on banding's merits, especially across and within countries. For example, most of the US,[66] Switzerland,[46] Scandinavia[41] and Israel[67] have abandoned banding. Yet pockets of ongoing resolute support continue within Australia,[15] England,[57] Italy,[39] Belgium[47] and the US.[53,68]

This study has weaknesses. Its retrospective nature precluded better characterisation of comorbidities, and aftercare

was suboptimal in 16%. Routine physician and psychologist assessment is now mandatory in our assessment. In addition, the median three-year follow-up period is too short to determine the long-term efficacy of this procedure.

The study's strengths include that analysis was on an intention to treat basis, that placement technique and band-type were standardised, and that follow-up was high (343 of 347 patients; 98.5%). In addition, factors associated with failure were identified that can guide the practice of those using lap banding.

## Conclusions

Bioring® banding is safe. It achieves moderately good weight loss and resolution of non-insulin dependent diabetes in the mid-term. It is not an ideal option for all patients. We have identified some patients who are best referred for a different procedure. Although slippage remains problematic, Bioring® banding still has a place in bariatric surgical options particularly in those with a BMI < 40 kg/m$^2$.


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### *Conflict of interest*

The authors declare no conflict of interest.

### *Ethical approval*

Ethics approval was obtained for this retrospective observational study from the University of the Witwatersrand Human Research Ethics Council (Protocol no: M180804).


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