COMPARISON OF CLOSURE VERSUS NON-CLOSURE OF BUCCAL MUCOSAL DEFECT AFTER GRAFT HARVEST IN URETHROPLASTY – PRELIMINARY RESULTS

Hypothesis / aims of study
Management strategies for urethroplasty can be standardized to some degree based on the anatomical position of the stricture, however, patient characteristics, disease characteristics and previous surgical intervention assessment plays an important role in stricture management. Utilisation of buccal mucosa was initially described by Humby in 1941 but popularised in 1992 and 1993 (1) as an easily accessible, durable substrate with high capillary concentration. The graft harvest protocol has been clearly identified in multiple studies (2), with importance placed on avoidance of Stenson’s duct, which resides lateral to the second molar in the maxilla. Post-operative pain from the oral mucosal defect has been compared to the pain from the perineal wound and the former was found to be minimal. Further oral complications have been described in small series with reported rates of 0-8.3%. There have been a few randomized control trials focusing on the closure of the mucosal defect (3). We hope to prospectively analyse the improvement of post-operative morbidity following closure versus non-closure of oral mucosa following graft harvest and present our preliminary findings.

Study design, materials and methods
This is a randomized non-blinded study. Patient were included if they were male, had a single stricture of any aetiology amenable to buccal mucosal augmentation, stricture length no greater than 5cm. Men were randomly allocated to closure or non closure using a sealed envelope system. The envelope was not opened until the graft was harvested. Only two surgeons were involved in this study. Neither the reserachers nor the participants were blinded. Our aim was to show an improvement in morbidity in the closure group.

Buccal mucosal graft was harvested from the left cheek. Stenson’s duct was marked and the graft was outlined. All grafts were 1.5x5cm. The submucosa infiltrated with bupivacaine: Adrenaline 1:2 000 000 solution. The graft margin was sharply incised and bipolar diathermy utilized to cauterize the bleeding sites. If the patient was randomized to primary closure, it was achieved with 4-0 vicryl rapide suture in a continuous stitch. In patients in the open arm the defect was soaked in an adrenaline soaked gauze for the remainder of the procedure and removed at the end.

A questionnaire with a 10 point visual analog scale for five parameters – pain, numbness, tightness, ability to drink and ability to drink – was administered to the patients preoperatively, at day 1 and 3, 3 weeks and 3 monthly thereafter. We present the first twenty patients in this series with a total follow up of 12 months.

Results
A total of 20 patients recruited from May 2008 to March 2011. They were randomized to two groups – closure and non-closure. There were 10 patients in each arm. Mean age of study population was 47.6 years with a range of 31 years to 68 years. All patients were followed up for a year. We are currently recruiting for this study. No statistical analysis for the precision of effect was completed prior to the commencement of the study. We aim to analyse the current data and extrapolate the number needed to recruit to reach statistical significance.

The the pain scores for the five parameters were average across the ten patients and plotted over time. The groups are compared below.
Interpretation of results
Pain scores, eating and drinking scores favour the closure group until 3 months after the procedure. Following this the curves merge and crossover. Numbness and tightness scores have similar curves for both groups. The tightness score favours the open group as expected with a difference noted even out to 12 months. The difference is not statistically significant (students paired t test two tailed \( p = 0.25 \)).

Concluding message
Our findings are not in keeping with the current published literature \(^6,7,9\). The early average pain scores are lower in the closure group with an increase noted late in follow up. The aetiology of this remains unclear. There are weaknesses in the study design with no statistical analysis completed prior to recruitment to ascertain the sample size required for significance. The study numbers are currently small, however there is a paucity of literature on this subject. The only comparable study was completed in 2009\(^1\) with 25 patients in each arm. We continue to accrue patients and aim to complete an interim analysis to identify the numbers in each group required for significant effect.

References

Disclosures
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