Hard palate cleft and oro-nasal fistula reconstruction utilising a resorbable sheet

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INTRODUCTION

The reconstruction of a cleft of the palate and the closure of an oro-nasal fistula (ONF) is a challenge for the surgeon and, not surprisingly, numerous techniques are available in the maxillofacial surgical armamentarium. These include primary palatoplasty methods to close the hard palate together with the soft palate, as well as secondary procedures to address recurrent oro-nasal fistulae.1 The most widely used techniques for closing the primary palatal cleft include the Furlow double-opposing Z-plasty² and numerous modifications thereof,³ the intravelar veloplasty,^{4,5} the Widmaier technique,6 the Von Langenbeck repair,7 the Veau-Wardill-Kilner repair,8 the Bardach technique9 and several Vomerine flaps,^{1,10} to name but a few. Adaptations of these techniques are also used in different combinations. The majority require substantial stripping of the hard palatal mucoperiosteum, resulting in associated morbidity, including pain and bleeding and restriction of growth.

There are varying degrees of success in achieving closure without the subsequent development of oro-nasal fistulae.⁸ Some of the several techniques for the closure of oro-nasal fistula have already been mentioned above. These can be divided into local, regional and distant techniques.¹ All of them have the common principle that multiple layers of tissue are sutured to facilitate closure. Local approaches include the commonly-utilised Von Langenbeck repair⁷ and the rotation finger-flap.⁹ Regional techniques include flaps from the tongue,¹¹ temporalis fascia¹² and facial artery musculo-mucosal flap (FAMM).¹³ Distant vascularised free tissue transfer is utilised under certain circumstances, especially when treating an unusually big defect. Most commonly used with predictable results is the radial forearm flap.¹⁴

This plethora of techniques speaks to the open opportunity to develop other approaches which may be more effective and predictable.

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ACRONYMS

FAMM: Facial Artery Musculo-Mucosal flap					
hP:	hard Palate				
hPsP:	hard Palate soft Palate				
LAP:	Complete unilateral cleft of the Lip, Alveolus and Palate				
ONF:	Oro-Nasal Fistula				
PdLLA: Poly-d and L-Lactic Acid					

Poly-D and L-Lactic Acid or "PdLLA" is an amorphous material that, once implanted into tissue, undergoes slow degradation by means of hydrolysis (absorbing water from the surrounding body fluids). Long polymer chains are broken down into shorter ones, and the D-lactides and L-lactides are transformed into carbon dioxide and water, which are completely absorbed into the surrounding tissues, leaving no residue. This process of degradation takes between six and nine months. On initial inspection, a PdLLA sheet or folio is a transparent, firm, almost plastic-like sheet. If heated in sterile boiling water, it can be moulded to and shaped into a specific contour (Resorb-X 0.3mm and 0.6mm sheet/KLS Martin, Germany).¹⁵

This paper introduces an alternative technique, using absorbable sheets of PdLLA in the closure of clefts of the hard palate and of oro-nasal fistulae.

MATERIALS AND METHODS

Thirty-one patients of the Facial Cleft Deformity Clinic at the University of Pretoria were recalled for a preliminary review using this relatively new technique (Table 1). Of these, fifteen patients had had oro-nasal fistulae (sixteen ONF's in total), and sixteen had presented with hard palate clefts.

The majority of the ONF group were cleft deformity patients who had developed fistulae after primary palatal repair surgery. One patient had a residual fistula following a selfinflicted gunshot wound. In each case, the ONF was surgically closed following a standard approach. After anaesthetic induction an oral splint was placed to gain adequate access to the fistula. A circumferential incision was made in the oral mucosa to create a nasal mucosal layer by dissecting, inverting, approximating and suturing the cut oral mucosal ends as a primary layer (Vicryl 4-0, Ethicon).

A pocket was created circumferentially, extending caudally at the hard palate bone, at least 2mm in depth, to facilitate a ledge upon which a patch of the resorbable sheet could be placed (PdLLA 0.3mm or 0.6mm sheet/KLS Martin). The sheet was moulded in sterile boiling water to conform to the

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Table 1: Patient details								
Patient details	Cleft configuration	Type of defect closed	Technique utilised in combination with PdLLA sheet	Complications	Follow-up period	Outcome		
7 month ♂	LAP (b)	Hard palate cleft	Superiorly-based vomer flap	None	14 months	Closure		
7 month ♀	LAP(b)	Hard palate cleft	Superiorly-based vomer flap	None	8 months	Closure		
18 month 3	Combi cleft (lip and soft palate)	Hard palate cleft	Circumferential dissection	None	10 months	Closure		
18 month ♀	hPsP	Hard palate cleft	Circumferential dissection	None	7 months	Closure		
18 month ♂	LAP(b)	Hard palate cleft	Circumferential dissection	None	7 months	Closure		
10 month ♀	LAP(u)	Hard palate cleft	Superiorly-based vomer flap	None	4 months	Closure		
19 month ♀	hP	Hard palate cleft	Circumferential dissection, Von Langenbeck closure	None	5 months	Closure		
19 month ♂	hPsP	Hard palate cleft	Circumferential dissection	None	4 months	Closure		
10 month 3	LAP(u)	Hard palate cleft	Superiorly-based vomer flap	None	4 months	Closure		
7 month ♀	LAP(b)	Hard palate cleft	Superiorly-based vomer flap	None	4 months	Closure		
8 month ♀	LAP(b)	Hard palate cleft	Superiorly-based vomer flap	None	3 months	Closure		
18 month ♀	hPsP	Hard palate cleft	Circumferential dissection	None	3 months	Closure		
12 month ♂	LAP(b)	Hard palate cleft	Superiorly-based vomer flap	None	3 months	Closure		
18 month 👌	hPsP	Hard palate cleft	Circumferential dissection	None	2 months	Closure		
4 year ♀	hPsP	Hard palate cleft	Circumferential dissection, Von Langenbeck closure	None	2 months	Closure		
7 month ♂	LAP(u)	Hard palate cleft	Superiorly-based vomer flap	None	2 months	Closure		
16 year ♀	LAP(u)	ONF	Circumferential dissection	None	10 months	Closure		
18 year ♀	LAP(b)	ONF	Circumferential dissection	Sheet dislodged at 3 weeks	10 months	Closure		
28 year 👌	LAP(u)	ONF x 2	Circumferential dissection	None	12 months	Closure		
13 year ♀	LAP(u)	ONF	Circumferential dissection	Very small residual ONF	6 months	Residual ONF		
19 year ♀	LAP(u)	ONF	Circumferential dissection	None	6 months	Closure		
13 year 👌	LAP(u)	ONF	Circumferential dissection	Sheet dislodged after 3 months	5 months	Closure		
69 year ♀	hPsP	ONF	Circumferential dissection	None	9 months	Closure		
7 year ♀	hPsP	ONF	Circumferential dissection	None	5 months	Closure		
30 year ♀	LAP(b)	ONF	Circumferential dissection	None	5 months	Closure		
35 year ∂	GSW	ONF	Circumferential dissection	None	4 months	Closure		
16 year ♂	LAP(u)	ONF	Circumferential dissection	None	4 months	Closure		
11 year ∂	LAP(b)	ONF	Circumferential dissection	None	4 months	Closure		
15 year ∂	LAP(u)	ONF	Circumferential dissection	None	3 months	Closure		
16 year ∂	LAP(u)	ONF	Circumferential dissection	None	3 months	Closure		
14 year ♀	hPsP	ONF	Circumferential dissection	None	2 months	Closure		

contour of the palate and a section cut to match the size of the prepared pocket. The patch was then placed onto the sutured nasal mucosal layer and the edges were tucked into the prepared pocket, covered by the flaps of oral mucosa. It was deemed important to ensure a tight fit into the pocket, as the segment preferably should not exhibit any mobility. Horizontal mattress sutures (PDS 4-0 Ethicon) were placed between the oral mucosal flaps in order to achieve additional security. Primary closure of the oral mucosa was not an objective and was not obtained, and thus only a single layer of tissue was actually repaired. Figures 1.1 to 1.5 show this specific surgical technique.

The sixteen patients presenting with clefts of the hard palate (hP) underwent similar procedures. Seven of the patients initially presented with clefts of the hard palate together with a cleft of the soft palate (hPsP) and nine had in addition clefts

of the lip and alveolus (LAP) (Table 1). The cases underwent reconstruction according to the Pretoria protocol for the reconstruction of facial cleft deformities. The patients with complete LAP or hPsP clefts underwent reconstruction of the soft palate at the age of five or seven months by means of a modified intravelar veloplasty. At the age of seven months for LAP and 18 months for hPsP, the residual hard palate cleft was closed. Closure by means of the described circumferential dissection was done, utilising the PdLLA patch, for patients with an isolated hPsP cleft (Figures 2.1 to 2.4). In patients requiring closure of the lip and anterior nasal floor, the procedures were done simultaneously. The standard technique utilised at the clinic, namely the inferiorly based vomer flap, could not be used in these cases, as the cleft was very narrow. A superiorly-based vomer flap¹⁶ was used instead, and a PdLLA sheet was placed at the level of the palatal mucosa, into a circumferential pocket created

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Figure 1.1: Hard palate cleft in an 18 month old patient with an isolated hard palate/soft palate cleft (hPsP) [soft palate was repaired at 7 months of age].



Figure 1.2: Circumferential dissection completed and nasal mucosal layer sutured.



Figure 1.3: PdLLA sheet contoured and marked to the size of the prepared pocket.

in a similar fashion to the technique previously described (Figures 3.1 and 3.2). Standard follow-up was done for all cases, between two to fourteen months post-operatively.

RESULTS

All patients recovered uneventfully. On average, the patients were discharged from hospital one day earlier than patients who had undergone different procedures for similar complaints. The PdLLA sheet of two patients became displaced three weeks and three months post-operatively. The ONFs, however, remained closed and exhibited no air or fluid leak. One patient presented with a very small (<1mm) residual ONF that occasionally lead to nasal regurgitation of fluid. The rest of the clefts and ONFs remained closed, yielding a 97% success rate (Table 1). On follow-up, the sheet was still visible in certain cases, and then generally had a clear appearance, except for one case that displayed as milky-white (Figure 4).



Figure 1.4: Prepared PdLLA sheet inserted. The nasal mucosal layer and sutures are visible through the sheet.



Figure 1.5: Oral mucosa sutured over PdLLA sheet.



Figure 2.1: Diagram of an oro-nasal fistula/residual hard palate cleft.

DISCUSSION

Luo and co-workers¹⁷ were the first to propose a technique whereby a PdLLA sheet is used as an additional layer in hard palate closure in conjunction with closure of the soft palate. They utilised a 0.5mm sheet during the closure of complete unilateral clefts (LAP), as a secondary procedure following the closure of the lip. They had two unsuccessful cases in a series of 32. Sader and co-workers¹⁸ published a series of 14 cases of ONF treated successfully by means of a technique very similar to a Von Langenbeck palatal repair, but with the addition of a resorbable collagen membrane (Geistlich Bio-Gide) as an interpositional graft inserted onto the repaired nasal mucosal layer. The utilisation of a membrane or PdLLA sheet together with a Von Langenbeck's repair appears to be superfluous. Lateral releasing flaps to allow for a central closure results in additional morbidity.

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Figure 2.2: Diagram of the dissection and creation of the pocket.



Figure 2.3: Diagram of the insertion of the PdLLA sheet.



Figure 2.4: Diagram of the sutures to secure the PdLLA sheet. The oral mucosal flaps are not approximated together.

This surgical technique described in this article has several advantages. The dissection required for creating the nasal mucosal layer and circumferential pocket for the sheet is far less extensive than that involved in the majority of previously described techniques available to close an ONF or hard palate cleft, resulting in a relative easy procedure, and saving in surgical time. There is less suturing when compared with other techniques. Furthermore, the hard palate is not extensively stripped of its mucoperiosteum, a substantial benefit for the growth disturbance of the maxilla. The limited palatal stripping



Figure 3.1: Diagram of a unilateral superiorly-based vomer flap.



Figure 3.2: Diagram of a PdLLA sheet placed in conjunction with a superiorlybased vomer flap.



Figure 4: Nine month post-operative image of a patient who presented with a bilateral complete cleft. The left side of the hard palate cleft was closed by means of an inferiorly-based vomer flap at the age of five months, together with closure of the soft palate. Although the palate is completely closed, groove-formation is noted on the left and the mucosa is unkeratinised. The right side of the hard palate cleft was closed at seven months of age (at the time of lip closure), utilising a superiorly-based vomer flap with PdLLA sheet. Note that keratinisation of the palatal mucosa on the right occurred as the sheet resorbed and no groove formation is seen.

in both the growing and the full-grown patient also results in less bleeding, less post-operative pain and earlier discharge from hospital. Last-mentioned is an additional cost saving. The use of the PdLLA sheet in conjunction with a superiorlybased vomer flap helps prevent "groove" formation which is otherwise often seen in these cases (Figure 4). This is made possible by preservation of the blood clot found between the vomer flap and the sheet, which allows for granulation of the clot. There also appears to be creeping of keratinised epithelium along the PdLLA sheet, which results in keratinised palatal mucosa, instead of the unkeratinised mucosa often seen after hard palate repair utilising an inferiorly-based vomer flap.

The use of a resorbable PdLLA sheet with a minimally surgically invasive technique may therefore be introduced as an alternative method for the successful closure of narrow ONFs and small hard palate clefts. This is a preliminary report and further long term follow-up is necessary to confirm inclusion of the approach in the list of reliable techniques which may be used in ONF and narrow hard palate cleft closure.

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