A PILOT STUDY OF THE SIMULTANEOUS USE OF DERMAL FILLER FOR RESTORATION OF DEFICIENT PAPILLAE AND ENAMEL MATRIX DERIVATIVE FOR ROOT COVERAGE IN CONJUNCTION WITH MINIMALLY INVASIVE SURGERY: PATIENT REPORTED OUTCOMES

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science Periodontology

Faculty of Dentistry
University of Toronto

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Abstract

Gingival recession, including interdental papilla loss, is considered by most patients as aesthetically unpleasant. Yet, in most instances, no treatment is available. Our aim was to develop a minimally invasive and predictable approach to treat papilla deficiencies and gingival recession. We hypothesized that, following the formation of a subperiosteal space, dermal filler administration into deficient papillae and a coronally advanced flap with enamel matrix derivative application to exposed roots will provide significant improvements in patient satisfaction with papillary fill and root coverage. Six months following treatment there was a significant increase in patient-satisfaction regarding improvement of gingival deficiencies shown by a mean increase in visual analogue scale (VAS) measurements of 68.3% (p<0.01; CI=52.11-84.51). Mean root coverage and papilla fill were 60.4%±43.3% and 1.3mm±0.7mm, respectively. This novel surgical technique demonstrates successful restoration of deficient interdental papillae with or without gingival recession and perhaps more importantly, a dramatic improvement in different patient-based-outcomes.
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Abbreviations

CAL – Clinical attachment level

EMD - Emdogain®

HA – Hyaluronic Acid

SCTG- Subepithelial connective tissue graft

Cemento-enamel junction (CEJ)

VAS(s) - Visual analogue scale(s)
Chapter 1: Introduction

The treatment of papilla defects and gingival recession is an ongoing problem facing patients and clinicians alike. The surgery involved during for the correction of these defects makes most patients consider any form of treatment with trepidation. Even if a patient chooses to proceed with therapy, it can be challenging for clinicians to provide the aesthetic results that they and their patients desire. Several well-documented and successful surgical interventions have been developed in managing gingival recessions, but most of these techniques can be very invasive and painful as, in many instances, two separate surgical procedures are required (one for the recipient site and one on the palate for the harvesting of autologous donor tissue). Further, for papilla defects no predictable treatment is even available.

Our primary goal in this clinical trial is to develop a novel therapeutic modality to restore papilla defects, in the presence or absence of gingival recession. Interdental papillary loss is one of the most challenging problems in dentistry for clinicians to treat and, in many instances, requires an interdisciplinary approach involving the periodontist, restorative dentist and orthodontist. The correction of these defects has become even more difficult in the presence of implants. In order to address such a complex issue we conducted a clinical pilot trial that involves a relatively pain-free, minimally invasive, and predictable surgical approach to rebuild lost interdental papillary tissues and obtain root coverage in areas of gingival recession, with the use of a dermal filling agent (for the former) and enamel matrix derivative (for the latter). We hypothesized that following the formation of a subperiosteal space, dermal filler (Juvéderm®) administration into deficient papillae and the use of enamel matrix derivative (Emdogain®) application to exposed roots as an adjunct to the use of a coronally positioned flap will provide significant improvements in patient satisfaction with papillary fill and root coverage respectively. Restoration of isolated papilla defects will also be obtained through localized subperiosteal papilla augmentation, using a non-animal derived hyaluronic acid osteoid-overlay. First, in order to evaluate this novel treatment modality, we will provide a thorough review of the biological nature of the interdental papilla, how papilla loss and gingival recession may occur and the current and limited evidence on managing such defects. In addition, we will present a unique approach for the assessment of clinical outcomes, by using patient-based-outcomes that, although subjective in nature, can be quantified with visual analogue scales [VAS(s)].
Chapter 2: Literature Review

2.1 The Interdental Papilla

2.1.1 The Interdental Papilla and its Role and Impact on Dental Aesthetics

There is an increasing awareness amongst patients regarding the aesthetic appearance of their dentition. These aesthetic concerns also encompass the health and appearance of the gingival tissues surrounding the teeth and/or dental implants. Periodontal plastic surgery is a significant component of aesthetic dentistry and was first described by Miller in 1993 as “surgical procedures performed to prevent or correct anatomic, developmental, traumatic or disease-induced defects of the gingiva, alveolar mucosa or bone.”4,11,12 Thus, periodontal plastic surgery includes the treatment of gingival recession and papilla deficiencies. In most cases, patients present with gingival recession or papilla loss secondary to aggressive tooth brushing or a history of periodontal disease, including treatment of that disease.4 Some studies have even shown that these conditions can simply be related to a patient’s age or sex.13 The interdental papillae of the anterior maxillary dentition is the most aesthetic area in a patient’s mouth. On average, 91% of patients show the interdental papilla upon smiling and even patients with a low smile line still show interdental papillae 87% of the time.14,15 Moreover, it has been documented that there is a significant psycho-social impact related to compromised aesthetics of a patient’s teeth and gingival tissues, so this is not merely a frivolous issue.16,17 There are even concerns relating to one’s ability to obtain a job, when there are significant problems with dento-alveolar aesthetics.18 This is concerning, as close to 50% of patients have been found to have some sort of papillary deficiency.19 When determining the impact of these defects on patients in comparison to other dental aesthetic concerns, patients rated “black triangles” as a significantly displeasing aesthetic factor, ranked only behind the presence of visible caries or an exposed crown margin.20 Both patients and general dentists consider embrasure spaces caused by loss of or damage to the dental papillae as unattractive and non-ideal, in comparison to those with healthy papillary volume.21 This issue is even more relevant around dental implants, where it has been reported more than 60% of papillae surrounding implant-supported crowns may not completely fill the embrasure space.22 In addition to compromised aesthetics, loss of the interdental papilla can have negative consequences including the development of caries, food or plaque accumulation, and altered
A healthy papilla is also required to provide a protective barrier for the underlying periodontium.\textsuperscript{24}

### 2.1.2 Anatomy of the Interdental Papilla

In a healthy periodontium, the gingiva fills the space between teeth and implants up to the apical extent of the contact point. This gingiva is called the “interdental gingiva or gingival papilla” and lies within an interdental triangular space called the embrasure.\textsuperscript{25} It is pyramidal in shape, with its tip extending to the apical extent of the contact point (See Figure 1). As one proceeds posteriorly, the interdental contact points broaden buccolingually, creating a gingival col between the two dental papillae on the facial and lingual surfaces. The col has non-keratinized epithelium that is more permeable than the keratinized gingiva from which it extends. Its formation is due to the combination of both junctional epithelia of the adjacent teeth or implants. The col is an area with increased susceptibility to toxic substances and physical trauma and is often the site where disease initiates, resulting in destruction of the periodontal apparatus.\textsuperscript{25}

### 2.1.3 Possible Risk Factors for Interdental Papilla Loss

Several factors may contribute to the presence or absence of papilla fill. It has been proposed that ideal papillary fill is significantly influenced by five main factors: “age, tooth form/shape, proximal contact length, crestal bone height and interproximal gingival thickness.”\textsuperscript{26} Complete papillary fill appears to occur under the following conditions: young adults with a favourable crown width/length ratio of $\geq 0.87$, a distance from the bone crest to the contact point of $\leq 5$ mm, a gingival tissue thickness of $\geq 1.5$ mm and a contact length between adjacent teeth of $\geq 2.8$ mm.\textsuperscript{7,26} Interestingly, papilla height has been shown to decrease by about 0.012 mm with each additional year of age.\textsuperscript{26} This papillary tissue loss can begin at early as 30 years of age.\textsuperscript{13} In addition to age, the sex of an individual has also been associated with papilla loss. Individuals aged 65 and older and those who are male are more likely to have deficient interdental papillary tissue.\textsuperscript{19} Several studies have evaluated the effect of the vertical distance from the height of crestal bone to the contact point on the presence of interdental papillae. The ideal distance from the contact point between two teeth and the interdental alveolar crest was found to be $\leq 5$ mm and when this dimension was satisfactory, complete interdental papillary fill was present 98\% of the time.\textsuperscript{27}
Complete papilla fill is also most likely to occur where interproximal heights and widths are either: 4mm x 1.5mm, 4mm x 2mm, 4mm x 2.5mm or 5mm x 1.5mm. As the interproximal distance between roots increases, there is a corresponding decrease in papilla fill. Lastly, a strong association between a thick periodontal biotype and the presence of interdental papillae of the maxillary anterior dentition in comparison to thin periodontal biotype has been demonstrated.

Around endosseous implants, the presence of a ‘reasonable’ papilla is dictated by the bone level of the adjacent tooth. Salama et al. concluded that up to 4.5mm of interproximal papillary tissue height could be achieved when the inter-implant distance was no greater than about 1.5mm. Thus, the horizontal distance between a tooth and an implant or two implants also contributes significantly to the presence or absence of papilla fill. In the presence of two adjacent implants, the ideal horizontal spacing and vertical distance from the alveolar bone crest to the contact point to achieve papillary fill is 3-4mm and 3mm, respectively. This correlates well to earlier studies by Tarnow and colleagues who showed that the ideal distance between two adjacent implants for inter-implant bone height and resultant papillary fill was 3mm and that the mean height of papillary tissue between two implants was 3.4mm. Additional potential risk factors associated with papilla loss are a history of periodontal disease, large embrasure areas and root angulations.

### 2.2 Classification Systems for Papilla Defects and Gingival Recession

#### 2.2.1 Nordland and Tarnow’s Classification for Papilla Defects

A classification system to interpret and describe papilla defects was first proposed by Nordland and Tarnow (See Figure 1). This system is based on the position of the interdental papilla in regard to the contact point between two adjacent teeth. As already discussed, the dental papilla should occupy the entire space between two adjacent teeth with no opening between the papilla and the most apical extent of the interdental contact point (i.e. for best aesthetic impact). In class I defects, the papilla is apical to the interdental contact point, but coronal to the interproximal CEJ. In class II defects, the papilla is apical to the interproximal CEJ, but coronal to the facial
CEJ. Class III defects are the most severe. In these circumstances the papilla has receded below the level of the facial CEJ.

**Figure 1** Illustration of interdental papilla and classification of papilla defects first described by Nordland and Tarnow in 1998.36

2.2.2 Miller’s Classification for Gingival Recession

Four levels of gingival recession have been established.37 In class I and II recession defects there is no interdental bone loss. The gingival recession in a class I defect does not extend apical to the mucogingival junction, while in a class II defect the level of recession extends to and/or beyond the mucogingival junction. In comparison with class II defects, the level of gingival recession in class III defects is the same. However, in these defects interdental bone loss is present and extends apical to the CEJ. In class IV defects interdental bone loss has progressed to a level in which the position of the gingival tissues is now coronal to the interdental bone. Overall, the best post-surgical outcomes for management of recession and the achievement of the greatest amount of root-coverage (100%) occur with pre-treatment class I and II recession defects. Conversely, when Class IV defects are present, it has been shown that little to no stable root coverage can be achieved.37
2.2.3 Relevance and Impact of Classification Systems

Currently, the overall predictability for the reconstruction of deficient interdental papillae is poor. Regardless of the surgical treatment described, there have been no reports of consistent, effective and long-term success in papilla regeneration of any type of papillary defect.\textsuperscript{4,36} Even when the treatment of these problems have provided beneficial results, one must consider that most approaches used to evaluate outcomes presented data that were essentially non-parametric, making statistical analysis, along with assessments related to clinical significance, difficult at best. It is also important to note that, in most cases, only clinical measurements/scales were utilized to assess treatment outcomes. These approaches overlook patient-based-outcomes including, but not limited to, pre- and post-treatment satisfaction with appearance of gingival tissues. Evaluation of these patient-based-outcomes is possibly even more important than findings derived from clinical indices or measurements.

2.3 Treatment of Gingival Recession

2.3.1 Tunneling Techniques

Zabalegui et al.\textsuperscript{38} helped lay the foundation and principles for the use of soft tissue tunneling at the recipient site for root coverage. In general, a split thickness flap is made in the area of gingival recession and the overlying tissues are released beyond the mucogingival junction as well as interdentally underneath the dental papilla. This flap is not reflected. Once the tissues have been mobilized to the point where there is no tension, they are then positioned coronally over the exposed roots to cover the area of recession. This type of ‘passive’ or tension-free release is obtained in order to insure, as predictably as possible, that there will be no apical migration of the flap and concomitant re-exposure of the root surface during and/or after healing. Once this is achieved, a connective tissue graft (usually derived from the palate) or acellular dermal matrix is teased gently into place under the released gingival tissue and secured with non-resorbable sutures. Sutures may also be placed in the overlying mobilized tissue for proper positioning over the root. This procedure has been modified over the years and has been proven to achieve a good degree of root coverage, especially when dealing with multiple sites of
recession defects at adjacent teeth and even in the presence of Miller class III recession defects.\textsuperscript{39,40}

Two recent modifications of the tunneling technique focus considerably on the development of a less invasive approach. The majority of tunneling procedures require the use of intra-sulcular incisions at the gingival margin in the area of recession, which results in unavoidable trauma and occasionally even in perforation of the tissue at the recipient site. The \textit{vestibular incision subperiosteal tunnel access} or “VISTA” technique uses an access incision 5-10mm in length within the attached and unattached mucosa away from the gingival margin of the teeth with recession.\textsuperscript{41} This allows for minimal trauma to the treatment site during subperiosteal release and provides a portal for graft placement. However, the subperiosteal access incision design used in the VISTA technique has been considered by others as too large.\textsuperscript{42} Hence, an even less invasive approach has been developed that requires only a 2-3mm entry incision.\textsuperscript{42}

\textbf{2.3.2 Newer Method for (Development of) Root Coverage and Repair of Interdental Papillae}

Using the various techniques described above, in addition to other approaches, we have developed a novel minimally invasive tunneling method for root coverage with simultaneous repair of the dental papilla, as needed. We have included the use of enamel matrix derivative (Emdogain\textsuperscript{®}; see Section 2.3.3) on exposed root surfaces as well as the use of dermal filler (Juvéderm\textsuperscript{®}; see Section 2.4.1) in surgically prepared spaces underneath deficient dental papillae. Our method allows for coronal advancement of tissues to reduce/eliminate recession defects and at the same time the repair of papillary defects.\textsuperscript{41,42}

\textbf{2.3.3 Enamel Matrix Derivative (EMD; Emdogain\textsuperscript{®}) for the Improvement of Root Coverage}

Enamel matrix proteins are the initiating factors that drive cementogenesis during development of the dental root and periodontium. Emdogain\textsuperscript{®} is composed of enamel matrix derivative (EMD) proteins that have been extracted and purified from developing porcine teeth.\textsuperscript{43} During surgery, EMD is applied to the exposed root surface following root debridement and conditioning (for surface demineralization purposes), in an attempt to replicate dental root development and facilitate periodontal regeneration. The use of EMD increases periodontal
regeneration in intraosseous defects. EMD is also useful for treatment of gingival recession without the requirement of a second surgical site for the harvesting of donor tissue (e.g. connective tissue from the palate).\textsuperscript{4,43}

2.3.4 Root Coverage Procedures with EMD

In relation to the success of root coverage procedures in general, it has been shown that mean root coverage success rates range from 51.5\% to 98.1\% for Miller class I and II recession defects and 54.8\% to 85.0\% for Miller class III defects.\textsuperscript{3} The application of EMD in combination with coronally positioned flaps provides a significant increase in post-operative root coverage as well as long-term stability in comparison with coronally positioned flaps alone.\textsuperscript{44,45} This decrease in post-operative relapse with EMD is most significant when treating Miller class I and II defects.\textsuperscript{45} Subepithelial connective tissue grafts (SCTG) are considered the gold standard in treating gingival recession and, when EMD is used in conjunction with a coronally positioned flap, comparable root coverage success rates as observed with SCTGs have been demonstrated.\textsuperscript{44,46} One significant advantage for the use of EMD instead of a SCTG is that, when using the former, a donor site is not required, thereby minimizing the amount of anxiety and discomfort experienced by the patient prior to, during, and following the surgical procedure. Furthermore, EMD has been proven to facilitate early post-operative wound healing by significantly decreasing bleeding on probing and post-operative patient discomfort.\textsuperscript{47} Given the above, we suggest that using EMD over exposed cementum after root planing and conditioning, followed by the coronal repositioning of gingival tissues will produce stable and aesthetically pleasing repair of recession defects. As well, we anticipate minimal postoperative discomfort, given that the surgical method itself is minimally invasive and that the EMD contributes to the reduction in postoperative pain and inflammation.

2.4 Dermal Fillers and the Treatment of Papillary Defects

2.4.1 Dermal Fillers

The utilization of dermal fillers in plastic surgery and dermatology has been an effective and long-standing therapeutic modality for treatment of a variety of aesthetic problems related to the
There are currently three classes of injectable dermal fillers primarily used in facial rejuvenation. These include hyaluronic acid (HA) derivatives, synthetic fillers and autologous fat. We have focused on the HA-derivative class of dermal fillers such as Restylane® or Juvéderm® in this clinical trial. HA derivatives are generally biodegradable fillers composed of a natural glycosaminoglycan called hyaluronic acid, which is found in human skin. When in contact with water, the hyaluronic acid swells, allowing expansion of the tissue contours within which it resides. Restylane is derived from the fermentation of streptococcus species and exists as a gel (suspended in liquid). It is composed of 20 mg/ml of HA with a mean particle size of 400 µm and is administered with a 30-gauge needle. There are approximately 100,000 of these particles/ml. Unlike Restylane, Juvéderm dermal fillers are not filtered based on the size of the HA moieties, but rather consist of a cohesive monophasic gel of cross-linked HA derived from Streptococcus equi by bacterial fermentation. Juvéderm Ultra and Ultra Plus are two of several different types of Juvéderm dermal fillers that are currently available. Juvéderm Ultra and Ultra Plus contain 24 mg/ml of HA, but the latter contains HA with about 2% greater cross-linking, which decreases water solubility. This allows for slower degradation of the material and increased longevity in situ. Juvéderm Ultra XC and Ultra Plus XC have 0.3% lidocaine added to them, to increase patient tolerability during administration.

Restylane was the first dermal filler, approved by the Food and Drug Administration (USA) in 2003, for use in the medical field. Juvéderm Ultra and Ultra Plus were introduced in the USA and Canada in 2006 and 2008, respectively. Since their introduction, dermal fillers have been used successfully for various procedures including lip augmentation and the restoration of facial volume loss as well as decreasing the presence of nasolabial folds, facial wrinkling and undesirable facial lines. Interestingly, tissue fillers have been used in dentistry to increase lip volume in order to obtain coverage of dental implants for patients with a high smile line or to aid in the retention of a removable prosthesis. Dermal fillers have also been injected into the gingival papilla to help restore papilla loss following implant surgery.

2.4.2 Treatment of Deficient Interdental Papillae Prior to Dermal Fillers

To date, several non-surgical and surgical methods have been developed to obtain papillary fill, but in many respects the results have not been overly robust. Non-surgical procedures pertain to
those that are prosthetic or orthodontic. Restorative techniques require that changes be made to the shapes of the teeth in the involved area, in order to close the interproximal spaces and minimize the presence of ‘black triangles’. However, the amount of closure that can be achieved is limited, as the crowns can become quite large, abnormally shaped and thus, unaesthetic in and of themselves; the impact on the ‘black triangles’ notwithstanding. Where significant periodontal defects are present, pink porcelain can also be added to substitute for gingiva and fill the defect. However, this approach is not overly satisfactory.

Orthodontic repositioning and extrusion are additional techniques in managing open embrasure spaces. Movement of the dentition closer together can help close the space. This can be enhanced through interproximal stripping of the interproximal tooth surfaces, allowing flatter contacts and a smaller area requiring papilla fill. However, caution is advised as moving teeth too close together could potentially result in unintended localized periodontal bone loss. Vertical extrusion of the involved dentition can cause concomitant coronal advancement of the periodontal apparatus increasing overall soft tissue height. This is a time consuming and tedious process, but has been shown to be successful when used under appropriate clinical circumstances.

From a surgical approach, pedicle flaps, free gingival grafts, connective tissue grafts and even repeated subgingival curettage have been used in attempts to surgically regenerate the interdental papilla. Unfortunately, the frail interproximal papillary tissue and lack of adequate blood supply results in the necrosis of any graft material used to augment interproximal papillae. Thus, most of these techniques have been unsuccessful or provide only mild improvements with significant morbidity to the patient. Beagle published one of the first case reports on surgical interdental papilla reconstruction. His technique involved the labial repositioning of a palatal split thickness flap into the interproximal papilla position. Carnio’s attempts to regenerate one interdental papilla required three separate surgeries at eight week intervals. Each surgery involved the harvesting and placement of a connective tissue graft in the interproximal area under the deficient interdental papilla.

There are also preemptive surgical techniques designed to prevent loss of the interdental papilla following treatment. Clinicians now anticipate papilla loss and attempt to minimize this through
their incision design at the time of surgery. The Split-Finger and ‘Palacci’ techniques are performed during surgery to manipulate and augment soft tissue in between dental implants at the time of surgery to not only preserve but also augment the interdental soft tissue and avoid the development of black triangles during post-operative healing.

Papilla-shaped titanium inserts have also been used to avoid the morbidity of hard and/or soft tissue augmentation. These titanium inserts are pyramidal in shape and come in an assortment of different sizes. They are screwed into the bone between two teeth with papilla loss. They provide bony support for the overlying soft tissue between two dental implants and can be easily adjusted to fit the size of the interdental space. The insert can be placed during implant surgery or anytime thereafter. This technique was never successful due to complications related to ongoing flap dehiscence and exposure of the papillary insert.

A recent systematic review in 2016 on available treatment techniques over the last six years for papilla defects identified only eight studies. None of the studies reviewed were randomized controlled trials and they all provided weak evidence for treatment at best. Interdental papilla fill varied exceptionally, with reductions of 0.73mm to 2.8mm in the distance of the tip of the papilla to the interdental contact point. In five of the eight studies, the placement of a subepithelial connective tissue graft with or without a coronally advanced flap was performed. No consensus or clinical recommendations could be made to assist clinicians in deciding on the best therapeutic modality.

2.4.3 The Novel use of Hyaluronic Acid Derivatives in Papilla Rejuvenation

Currently, the literature lacks strong clinical evidence suggesting that the use of dermal fillers in providing papilla rejuvenation is highly successful. Becker et al. published the first case report on the use of hyaluronic acid injections (Restylane®) in the restoration of minor papillary deficiencies adjacent to dental implants and/or teeth. Fourteen sites were treated in eleven patients. A total 0.2ml of Restylane was administered several millimeters apical to the papillae, using a 23-gauge needle, 2-3 times. This was followed by repeated injections of Restylane at three-week intervals with no more than three applications. Cases were followed for a 25-month period. Three sites had 100% fill while the remaining eleven sites had papillary fill ranging from
57-97%. The authors concluded that it was possible to obtain ‘modest’ improvements in papilla fill. Importantly it should be pointed out here that the investigators did not evaluate patient related outcomes.

Reconstruction of the dental papilla was attempted by others and followed the methods described previously by Becker et al.\textsuperscript{58,70} HA was injected into twenty-one deficient interdental papillae between natural teeth.\textsuperscript{70} Injections were repeated at three weeks and three months. By the six-month time-point, a statistically significant improvement in papilla fill of ≥50% was found in 43% of treated sites. In a more recent case series\textsuperscript{71} seventeen class 1 and 2 papilla defects associated with the natural dentition of nine female patients were treated. The investigators, using a 23-gauge needle, injected 0.2ml of cross-linked HA into sites with deficient papillae. These injections were repeated at three weeks and six weeks. Photographs were taken at baseline (i.e. prior to treatment), and photographs taken four- and six-months after treatment. The investigators demonstrated a statistically significant mean increase in papilla height in the treated sites by six months (0.5mm). About 66% of patients indicated that they would be willing to have this type of procedure done again, if necessary. The patient assessments implemented in this study highlight an important step towards the use of patient-based outcome measures.

Due to concerns regarding the assessment of papillary fill following dermal filler injection, Lee et al.\textsuperscript{61} introduced the ‘photographic standardization device’ and ‘injection-assisted device’ for more precise analysis of papilla dimensional changes and hyaluronic acid administration.\textsuperscript{61} A total of forty-three maxillary anterior sites were treated among four males and six females. The investigators utilized an injection-assisted device with a 30-gauge needle to introduce 0.002ml of hyaluronic acid gel up to five times for a total of 0.01ml of HA. Each injection was performed three weeks apart and administered ‘as needed’ to achieve complete papillary fill. With the aid of the ‘photographic standardization device’ changes in black triangle area, height, and width were calculated. The data showed that there was a 0.2mm\textsuperscript{2} reduction in black triangle area, along with a reduction of 0.71mm and 0.32mm in black triangle height and width, respectively. The number of injections required ranged between three-four times and this produced a mean papillary fill of 92.6%. Furthermore, of the forty-three treated sites, twenty-nine had complete fill.
Lastly, the first and only randomized controlled trial performed studied the effects of HA injections compared to saline injections into the deficient papillae of twenty-two patients. VASs were also included to quantify patient-reported outcomes. In this study, it was not possible to demonstrate any differences in the morphological characteristics of papillae in either the control or treatment groups, even up to and including a post-treatment time point of six months. Patients experienced moderate pain for both saline and HA injections, as demonstrated in pain levels averaging between 50-60 using a 100mm VAS assessment on pain during injection. However, significantly more discomfort was associated with the injection of HA in the first week following treatment (VAS of 28 for HA and 5mm for placebo). When measuring the aesthetic impact of treatment for patients, their general perception of improvement was somewhat modest as based on VAS measures with satisfaction scores of <30mm. Interestingly, this response fits with the clinical findings reported for this study.
Statement of the Problem

Various surgical interventions are available for the management of gingival recession, but these methods are invasive and painful, often requiring two surgical sites (donor and recipient) and in many instances fail to provide complete root-coverage. Moreover, most papilla defects and their associated ‘black triangles’ remain untreatable. Although these ‘black triangles’ appear quite small from a clinician’s viewpoint, they seem to have a rather significant impact on oral health satisfaction for patients. This variability in results and lack of success along with the associated morbidity from these procedures highlights the need for less invasive, less painful and more predictable approaches to manage root exposure and papilla deficiencies. It is our intent to develop such a procedure, as described below, with the use of EMD and a dermal filler.

The application of dermal fillers in dentistry is in its infancy. HA has been used recently for treatment of deficient papillae, but the results have been generally unpredictable with only modest improvements at best. In this regard, previous investigators utilized direct injection of dermal fillers into deficient papillae without the creation of a ‘tissue space’ that would facilitate the delivery and retention of the dermal filler into the site. Thus, one might have predicted minimal success using these types of approaches since, unlike in the pliable skin where dermal fillers are most commonly used, the interdental papillary tissues are dense and immobile. This underscores the rationale for the development of the approach described here. It is our hypothesis that a subperiosteal tissue space underneath the papilla must be created first, in order to receive the dermal filler and thereby produce visible and substantial morphological changes.

Thus, the aim of this pilot study was to develop a minimally invasive and predictable approach to restore papilla deficiencies and correct gingival recession either concurrently or separately, depending on the clinical situation. Our clinical trial investigates the restoration of papilla deficiencies and correction of gingival recession using a surgical technique that involves the use of modified HA dermal filler (Juvéderm®) for reconstruction of deficient interdental papillae as well as enamel matrix derivative (Emdogain®) for obtaining root coverage. It is our intention to use Juvéderm to rebuild deficient papillae and to utilize EMD to promote root coverage in a single procedure. The surgical technique in this clinical research trial is based loosely on the methods described by Zadeh \cite{Zadeh} and Chao \cite{Chao} and should be considered to be a minimally invasive...
surgical approach. We predict that localized administration of a dermal filler and EMD, following the formation of a subperiosteal tissue space to receive the material, will provide root coverage and the restoration of interdental papilla deficiencies.
Chapter 3: Materials and Methods

3.1 Human Subjects

The calculated sample size for this study was based on a model described by Norman and Streiner.\textsuperscript{73} We predicted a minimum 30\% improvement (effect size) in gingival aesthetics from our VAS scores to be clinically significant. Based on this improvement along with an anticipated standard deviation of 25, a significance of $\leq 0.05$ and a power set at 0.9, we estimated a sample size requiring at least 15 patients.\textsuperscript{73,74} Prior to patient recruitment, this clinical pilot study received approval for scientific merit and ethics from the University of Toronto’s Faculty of Dentistry and Research Ethics Board. All patients were selected from the Graduate Periodontics clinic at the Faculty of Dentistry, University of Toronto. Overall, twelve patients (9 females and 3 males) were screened. This was quite close to our initial convenience sample size of fifteen participants. We did not use a ‘control’ group, but instead all comparisons were performed pre- and post-operatively.

3.2 Inclusion and Exclusion Criteria

Specific inclusion and exclusion criteria are highlighted below and were evaluated via a comprehensive medical history form (Appendix A):

- Patient inclusion criteria
  - Eighteen years of age or older and willing to proceed with all treatment and follow-up appointments
  - Presence of localized areas of recession and/or interdental papilla loss
  - No contraindications to periodontal surgery
  - Presence of class 1 or 2 papilla deficiencies and class 1, 2, or 3 recessions

- Patient exclusion criteria
  - Active periodontal disease or presence of gingivitis in the proposed surgical area
  - Pregnant women
  - Patients with severe systemic disease (we enrolled patients with an American Society of Anesthesiologists’ physical status classification of 1 and 2 only)
  - Smokers or patients with a history of smoking in the past 5 years
3.3 Materials

Materials: periodontal UNC-15mm probe, 5% lidocaine topical anaesthetic, 2% lidocaine with 1:100 000 epinephrine, 0.5% bupivacaine with 1:200 000 epinephrine, surgical scalpel, 15C blade, Allen end-cutting intrasulcular knife, ultrasonic piezoelectric scalers, 7/8 Younger-Good and 4R/4L Columbia curettes, Rhodes back-action periodontal chisel, HA (Juvéderm®), EMD (Emdogain®), cyanoacrylate cement (Histoacryl®), ethylenediaminetetraacetic acid (EDTA) (Pref-Gel®), 25 µl pipette tip, cotton swab or Q-tip, 6.0 polypropylene suture, camera.

Figure 2) Juvéderm® and Emdogain® used for clinical treatment

3.4 Examination and Surgical Protocol

3.4.1 Initial examination and informed consent (30 minutes)

- Patients being treated in the Graduate Periodontology department who fell within the proposed study groups met with the primary surgeon for an initial exam and informed consent process (for consent meeting script – Appendix B).
- Patients were provided with detailed information regarding the study design, goals and time-frame. Expectations of each participant were reviewed. All associated risks and benefits were outlined.
- Patients were informed that they had the right to withdraw from the study at any time with no consequences.
- An information letter, which included all details regarding the clinical trial was given to the patient (Appendix C).
- If patients were interested in participating in this study, written consent was obtained to proceed with the clinical examination (Appendix D)
• Initial clinical measurements were obtained:
  o buccal recession measured from cemento-enamel junction (CEJ) to free gingival margin at the mid-facial and line angles of each tooth
  o distance from the tip of papilla to interdental contact point
  o pre-operative photographs of proposed surgical site (not-standardized)
  o radiographic assessment of bone levels
• Following initial examination and determination of sites requiring treatment, patients who met the inclusion criteria were provided the opportunity to participate in the study.
• Patients had the opportunity to ask any questions regarding the study and detailed responses were provided. We offered a telephone number to each patient, so that they could contact the PI or other investigators, if they had additional questions.
• If the patient agreed to proceed with treatment, informed consent was signed (Appendix E). A copy of the signed consent form was given to each participant.
• Patients were provided with post-operative instructions (written and verbal) that they would be required to follow after surgery (Appendix F).
• Patients completed the pre-operative assessments in the case report form (Appendix G).

3.4.2 Surgical Protocol
On the day of surgery, the surgeon reviewed the previously signed consent form with the patient and asked the patient if he or she had any further questions. Once verbal consent to proceed was given, topical lidocaine 5% was applied in area of the surgical site. Buccal and lingual infiltration using 2% lidocaine with 1:100 000 epinephrine and 0.5% bupivacaine with 1:200 000 epinephrine was administered. Scaling and root planing of the teeth involved with ultrasonic piezoelectric scalers and hand instruments was performed. A 3-5mm horizontal incision was made in the alveolar mucosa at a minimum of 2mm beyond the mucogingival junction. Using the incision as access, a subperiosteal tunnel was created toward the area of recession and deficient interdental papilla(e), while leaving the interdental and marginal tissue intact. Juvéderm was administered into the papilla(e) and the tissue space underneath to achieve ideal papillary fill after the preparation of the surgical space was completed. Cyanoacrylate was then used to seal the free gingival margins surrounding the papilla(e) with a 25µl pipette tip (gently tap or push on pipette to control release, soak cotton swab in saline and dab area to facilitate set). This was done to
prevent ‘leakage’ of the HA from the treated site. Cyanoacrylate was not used if papilla defects were treated in combination with recession (in these cases a sling suture was placed instead, to coronally advance the gingival margin and papilla). The exposed root cementum was conditioned with EDTA followed by placement of EMD and coronal repositioning of the gingiva/alveolar mucosa over the area of recession. A 6-0 polypropylene sling suture was used to maintain coronal advancement. During the surgical procedure, additional dermal filler was administered into the interdental papilla as needed, in order to maintain the best papillary correction. An average of 0.2-0.6 ml of dermal filler was required per papilla, depending on the extent of the papilla loss. Post-operative instructions were reviewed verbally in detail, and a written copy was provided (Appendix F). Figure 3 below provides a visual demonstration of the surgical technique.

![Figure 3](image)

1) Root planing of the exposed root surfaces is performed. A 3-5 mm horizontal incision is made in the alveolar mucosa at a minimum of 2 mm beyond the mucogingival junction.

2-3) Through this access incision the periosteum is released towards the area of recession and under the deficient interdental papilla(e) (interdental papilla remains intact).

4) Juvéderm is administered into the papilla(e) to achieve ideal papillary fill. Straumann PrefGel® is used to condition the exposed cementum followed by placement of EMD and coronal repositioning of the gingiva and alveolar mucosa over the area of recession.

5) Cyanoacrylate is used to seal free gingival margins surrounding the papilla(e) (not used if treating papilla(e) defects in combination with recession). A sling suture is placed to maintain coronal advancement with 6-0 polypropylene. Additional injections with Juvéderm into the interdental papilla(e) are performed as needed.
3.5 Post-Surgical Assessments and Data Collection

Treatment outcomes involved the assessment of aesthetics using VASs to measure an array of patient-reported/subjective outcomes. These scales were also used to assess clinician-based subjective assessments (Appendix G). Prior to completion of the clinical report-related VASs, patients practiced and familiarized themselves with the concepts associated with VAS-based measurements of subjective data. The practice sessions included the assessment of ‘blackness’ of four different box-shapes using VAS measurement. More importantly, patients were presented with clinical photographs demonstrating recession/papillary presentations ranging from those considered by the investigator to represent poor to excellent gingival appearances. Patients who were unable to provide appropriate VAS measures could be either re-trained or not be included in the study (this did not actually occur). VASs pertaining to post-treatment results included both the patients’ subjective perceptions as well as clinician-based assessments of aesthetic outcomes using pre- and post-operative photographs taken of the patients’ surgically treated areas. By using VASs, it was also possible to measure other secondary subjective outcomes including pain and tolerance of the procedure in its own right, as well as how this procedure was tolerated in comparison to previous periodontal treatments the patients might have had. The VAS-based outcomes were analyzed in such a way as to be able to differentiate and measure improvements in aesthetics as perceived by patients and clinicians regarding root surface coverage and/or interdental papillary fill. In all cases, patient information and dates of the pre- and post-operative treatment photos was concealed, which provided for blinding.

In addition to patient- and clinician-based subjective assessments, it was also considered critically important to use more commonly accepted measures to evaluate the outcomes of this surgical study. Initial recession and percent root coverage before and after therapy was measured. The pre- and post-operative distance from the tip of the papilla to the interdental contact point was used as an objective measure of papilla reconstruction/fill. All pre- and post-operative measurements, photographs and VAS assessments were performed by the same clinician. See below for the details of assessment at each follow-up appointment.

1) 1-2 week follow up – 30 minutes
   • Assessment of healing of surgical site and removal of sutures. Oral hygiene instructions. Answer patient questions or concerns.
• Measurements of recession, complete root coverage percentage, distance from papilla tip to interdental contact point.

• Post-op photographs for clinician and patient specific visual analog scale assessment of outcomes (pre- and post-operatively where appropriate) including, but not limited to, satisfaction with appearance of papillae, satisfaction of overall gingival appearance, success of root coverage and post-operative pain.

2) 6-week follow-up – 30 minutes

• Assessment of healing, provide supra-gingival debridement as needed. Hygiene re-instruction. Answer patient questions and concerns.

• Measurements of recession, complete root coverage percentage, distance from papilla tip to interdental contact point.

• Post-op photographs for clinician and patient specific VAS assessment of outcomes (pre- and post-operatively where appropriate) including, but not limited to, satisfaction with appearance of papillae, satisfaction of overall gingival appearance, success of root coverage and post-operative pain.

3) 6-month follow-up – repeat steps of 6-week follow-up

3.6 Statistical Analysis

Pre- and post-treatment VAS scores were recorded in tables for assessment and comparison. The following null hypothesis was considered to test our VAS assessment: there is no difference between the pre- and post-VAS assessments and papillary fill. We predicted that the creation of a subperiosteal tissue space followed by the administration of a dermal filler and EMD will lead to statistically and clinically significant improvements in the aesthetic appearance of either or both root exposure and papilla defects, as reported by patients and clinicians. The primary VAS score in testing this hypothesis was a question regarding patient satisfaction with papilla fill and/or root coverage. Secondary VAS scores addressed different exploratory outcomes of this novel surgical technique to help provide clinicians with a means of evaluating this technique further and establish new or adapt existing treatment modalities. Data obtained from the primary VAS scores and quantitative assessments were analyzed using paired sample t-tests with a significance level set at $\alpha = \leq 0.01$ for rejection of the null hypothesis.
Chapter 4: Results

4.1 Subjective Outcomes: Patient- and Clinician-Based

Seven females and two males (mean, 54.3±7.2 years old) among the 12 patients initially screened underwent treatment and completed the required follow-up period. One patient came back and underwent the procedure twice, resulting in ten cases among the nine patients. Primary and secondary VAS scores were the principal method used for assessment of patient-based outcomes, as noted above. The primary VAS outcome used to assess treatment success was the VAS response to the question: “How would you rate your papilla fill and/or root coverage?” (Table 1; Figure 4; Appendix G). There was a 61% and 68% improvement in patients’ perceptions of papilla fill and/or root coverage when comparing pre- versus post-operative appearances (60.7%; \( p<0.01 \); CI=42.0-79.3 and 68.3%; \( p<0.01 \); CI=52.1-84.5) at six weeks and six months after treatment, respectively. An even greater improvement was found when analysis was restricted to the treatment of Tarnow class 1 and/or Miller class 1 or 2 defects (Mean VAS increase of 65.8%; \( p<0.01 \); CI=46.7-85.0 at six weeks and of 70.6%; \( p<0.01 \); CI=47.3-94.0 at six months) (Table 1). A series of secondary subjective outcomes were also assessed (Tables 2-5; Appendix G). When patients were asked if they were happy with the overall aesthetics and if they thought the surgery was successful, the level of VASs showed satisfaction measures of 73% and 81% at six months, respectively. This increased substantially for both overall aesthetics (89.8%±19.0%) and treatment success (96.3%±5.1%) when analyzing only cases with pretreatment Miller class 1 and 2 recession defects and/or Tarnow class 1 papilla defects. Further, in most instances, patients who underwent this minimally invasive surgery indicated that they experienced less pain, increased procedure-tolerance, and faster postoperative recovery, as compared to their experiences with previous periodontal surgical procedures such as open flap debridement, gingival grafting and implant placement (Table 3).

When periodontists were asked to evaluate papilla fill and/or root coverage before and after treatment, their subjective clinical assessments of improvements were more modest than those reported by patients. The average VAS increase noted after surgery based on overall clinical improvement was 27% (VAS= 27.4%±6.2%). Similarly, when assessing whether treatment was
clinically successful, they rated it at a level of about 68% (VAS = 68.0±7.0%), but this still represented a substantial increase over baseline assessments (Table 6).

4.2 Clinical Measurements

Mean papilla fill of 61.8±26.7% was observed at six months, among the 26 treated papilla defects. This corresponded to a statistically significant mean increase in papilla size/fill of 1.3mm±0.7mm (p<0.01) (Table 7; Figure 4). In addition to this overall result, it was also noted that more than half of the treated defects resulted in ≥2/3 of papilla fill after surgery. The average amount of root coverage obtained was 60.4±43.3% in 52 treated sites, and 26 of the sites demonstrated 100% root coverage (Table 8). Simultaneous root coverage and papilla correction treatment did not alter outcomes for either clinical parameter.
Chapter 5: Discussion

To the best of our knowledge, this is the first clinical study evaluating the use of dermal fillers in the augmentation of deficient interdental papilla through the creation of a subperiosteal tissue space. It is also the first attempt at treating deficient papillae with dermal fillers at the same time as treatment of gingival recession using EMD. Our results indicate that both clinically and statistically significant improvements in interdental papilla fill can be achieved. We also demonstrate that the presence of both gingival recession and papilla deficiency should not be a deterrent to treatment.

There was a substantial improvement in patient satisfaction relating to the appearance of their gingival tissues (papilla fill and root coverage) following dermal filler injection and/or gingival coronal advancement. Even though we originally predicted that an improvement (effect size) in VASs of 30% pertaining to gingival aesthetics among at least fifteen patients would be required to reach significance, we achieved a statistically significant increase in patient satisfaction post-treatment with only 9/10 patients. Moreover, these results correlate well with our quantitative post-operative percentages and measurements in papilla fill and/or root coverage obtained, suggesting VASs used to measure subjective outcomes are reliable assessments of treatment success. According to the literature, VASs are considered as one of the best techniques for measuring levels of chronic and acute pain. They have also been used extensively to evaluate other subjective parameters involving patient perceptions. As in our study, VAS assessments was performed by using a 100mm scale anchored by particular descriptors that are considered to be opposites of one another. Patients’ ability to use these continuous scales to quantify subjective parameters is the key to their strength. This is in contrast to discontinuous scales that evaluate subjective outcomes using ratings based on numerical or verbal values. The power of VAS-generated data results is exemplified further by the difference between patients’ opinions related to improvements in gingival aesthetics following treatment, compared to those of periodontists. Patients were clearly more satisfied with post-treatment gingival aesthetics and overall success, highlighting the importance of understanding patient concerns and meeting their expectations. Perhaps there should be less of a concern that in many cases, ‘perfect’ clinical results cannot be obtained, since the ultimate arbiter of treatment success, when considering procedures in periodontal plastics surgery, is in fact the patient. It is interesting to note that what
a periodontist might consider as an acceptable or aesthetic result differs from the patients’ assessments. Contributing factors to this difference may be the fact that patients are usually more aware of the appearance of their papilla defects, fail to understand the difficulty in achieving papilla fill and the lack of treatment options available to them or they may have previously experienced unsuccessful therapy. Thus, we believe the improvements in our patient reported outcomes as per primary and secondary VAS scores confirm the true value of this novel and minimally invasive surgical technique. Furthermore, in our investigation, patients were trained in the use of a VAS to score gingival aesthetics (Appendix G). This training likely added an additional degree of confidence in the outcomes of VAS measurements obtained in our study as compared to VAS readings obtained from patients who would be otherwise unfamiliar with the use of a VAS. Other studies that implement VASs for assessing pain or aesthetics associated with papilla fill or root coverage do not report the use of pre-operative practice VASs for their patients.72,78 In these studies we don’t know whether the patients understood the concept of a VAS or how to complete them appropriately. In addition, it is important to emphasize that had subjective outcomes not been measured, it was still possible to demonstrate statistically and clinically significant improvements, based on clinical measures of treatment.

As reported in the literature, when carrying out treatment for recession, the clinical measurements show that root-coverage improvements can range from 51.5% to 98.1% for class I and II recession defects and 54.8% to 85.0% for class III defects.3 In our study, the average amount of root coverage achieved was about 60.4%±43.3%. Although this is on the lower end of the expected root coverage following treatment, we believe the true value of this surgical technique lies in the fact that one can treat root recession and papilla deficiencies concurrently and without the requirement of a donor site. The amount of papilla fill achieved six months following treatment in our study appears comparable to other studies. Through the simple injection of dermal filler into the papilla Becker et al. showed papillary fill ranging from 57-97%.58 Other studies report a ≥50% improvement in papilla fill among 43% of treated sites.70 Awartani and Tataakis71 treated Tarnow class 1 and 2 papilla defects in seventeen sites with a mean increase in papillary fill of 0.5mm at six months. The percentage of papilla fill reported in our investigation is similar to that reported by Awartani and Tataakis71. However, the average amount of papilla fill obtained in our investigation was 1.3mm±0.7mm; an almost 3-fold increase in comparison. This additional 0.8mm increase in papilla fill over six months suggests the
papilla defects treated in our investigation could have been more severe than those treated by Awartani and Tatakis\(^7\) (Table 7) and represents the potential for a greater effect, depending on the size of the defect being treated, using the methods described here.

We suggest that one of the important factors relating to generating more fill of deficient papillae in our study can be attributed to surgical release of the gingival tissue and creation of a subperiosteal space prior to insertion of dermal filler. When HA gel is ‘merely’ injected into a deficient papilla, it has been shown, using a randomized controlled trial approach, that there were no significant improvements in papilla fill compared to control (saline) injections.\(^72\) However, the failure to demonstrate a significant difference in this study could have also been related to the rather small sample size that was used, and perhaps to the somewhat limited injection protocol in comparison to other studies including ours (i.e. the investigators used a different injection technique and only a single follow-up injection at four weeks).\(^2\) Others have also suggested that detaching the gingiva by way of a tunneling procedure, prior to HA injection, could provide for mobilization of the soft tissue prior to injection, thereby producing a more satisfactory outcome.\(^72\)

When dermal fillers are used to treat skin problems (e.g. wrinkles), there is no need to create a surgical space. However, in the treatment of deficient dental papillae, as opposed to the skin, there are significant anatomical constraints that must be considered. In contrast to skin, gingival tissues, including the papillae, are firmly bound down to an underlying periosteal bed with very limited elasticity. Without this elasticity it is unlikely to be able to expand a deficient papilla using injections alone. By tunneling under the interdental papilla, we were able to release the interdental collagen-rich connective tissues, allowing mobilization for both coronal advancement and expansion of the papilla immediately following injection. All previous studies have relied on the ability of HA to expand the interdental papilla over time through its absorption of water along with the use of up to five separate injections to obtain meaningful results.\(^5,\)\(^6,\)\(^7,\)\(^15,\)\(^58,\)\(^60,\)\(^70-72\) By using the approach described here, similar clinical results (papilla fill) were obtained in a single surgical appointment. Furthermore, as noted above, the procedure was tolerated well by the patients.

When we treated papilla defects in combination with gingival recession, the gingival margin was
positioned at the level of the CEJ. We suggest that even more papilla fill, as well as root coverage might be achieved by advancing the gingival margin coronally past the CEJ, onto enamel. Indeed, this concept has been illustrated and discussed by others who obtained improved root coverage, when flaps were fixed at approximately 2mm beyond the CEJ. Therefore, we postulate that further advancement of the flap beyond the CEJ, even in areas without root exposure, could allow for the creation of a larger subperiosteal space, allowing for the introduction of more dermal filler and, subsequently, the development of even more papilla augmentation than demonstrated here or in other studies. We anticipate that, as shown by others, when the site heals, the ‘overextended’ gingival margins will recede back to their normal physiologic position, while the papilla would retain its increased size due to the dermal filler placed at the time of surgery.

Through clinical observation, we noted additional factors that might affect results such as the width of the interdental black triangle. In this regard, we observed that if the embrasure space was too wide or too narrow, papillary fill following HA injection was less likely to occur. This seems to correlate with more definitive findings by Lee and colleagues who demonstrated that defect dimensions including black triangle area, height and width appear to affect treatment success. When the area of the black triangle was 0.25mm² with a 1mm height and 0.5mm width, complete fill of the deficient papilla was most likely to occur. To the best of our knowledge, this is the first prognostic criterion proposed that clinicians may be able to use to predict future papilla fill for patients. In our study, the amount of hyaluronic acid we injected at each site ranged from 0.2-0.6ml. This was based on need and not on a pre-determined amount of filler to be utilized. Lee and colleagues demonstrated that using smaller injection amounts minimizes dermal filler loss, while providing additional injections increased the amount of papilla fill. There also appears to be no set limit to the number of injections that can be performed. All previous studies show that multiple dermal injections over time were required to obtain optimal results. However, this might be due to the fact that in these studies, a surgical space for placement of dermal filler (and also mobilization of the papilla itself) was not created.

Considering the biodegradable nature of dermal fillers such as Juvéderm, it may not be possible to achieve long-term stability. In this regard, a previous study showed that papillary improvements with the use of injected HA can be maintained for up to at least two years.
Thus, time will tell if, during maintenance therapy, the sites will need to be re-injected to regain the surgically created improvement. If additional therapy is required long-term, we suggest that treatment might consist of ‘touch-up’ injections only due to the presence of an already-established surgical ‘space’. With our surgical technique, patients appreciated significant improvements with high levels of treatment acceptance and tolerability. Therefore, even if surgery is necessary again at some point, this might not be perceived as being too onerous for the patient. Further, in regard to the potential need for re-treatment, it has been demonstrated in vitro that injection of cross-linked HA in reconstructed 3-D skin models induces an increase in fibroblast activity and production of type 1 and 3 procollagens. Results also indicate that HA may impact fibroblast regulation of MMP-1 secretion. Interestingly, Lee and colleagues found that when the distance from the alveolar bone crest to the interdental contact point was ≤6mm complete papilla fill was obtained. In comparison to Nordland and Tarnow’s classical study on papillary height, HA injections appear to promote an additional 1mm of papilla fill, possibly through collagen production, beyond the ‘normal’ physiological interdental papillary fill of 5mm. These assumptions are also based on HA’s role in tissue healing through enhancing cell proliferation, re-epithelialization, migration and blood vessel formation. Its ability to enhance wound repair results in reduction in scar tissue formation. In dentistry, HAs have been useful in the treatment of aphthous ulcers through a barrier effect with immediate reduction in soreness. There was also a decrease in the recurrence of these ulcers. HAs have even been shown to have potential anti-inflammatory effects in the treatment of gingivitis. With respect to papillary fill, some studies have shown improvements can be maintained over time while others indicate relapse does occur. For instance, Mansouri et al. found 10% of treated patients had 50% improvement at three months in comparison to 43% of patients at six months, and Becker et al. showed a 94% improvement in papilla fill over a span up to twenty-five months. However, Awartani and Tatakis found there was relapse in some cases four and six months post-treatment. Similarly, a small amount of relapse was evident in localized sites among some of our patients. This was not evident in our mean papilla fill at six weeks (61.2%±39.3%) or six months (61.8%±26.7%) because, over time, other sites had an increase in papilla fill (Table 7). If the dermal filler does degrade over time, then one would expect to see volume loss occurring in all treated sites. This was not the case in our study. Therefore, it is likely this relapse in localized sites can be attributed to a multitude of other factors such as the patients’ own post-operative care. In fact, one patient in our study who actually experienced relapse, admitted later
on to the repeated use of tooth picks in between her maxillary anterior teeth, including the area of treatment. Hence, control of patients’ habits would also seem to be critically important in order to ensure good treatment outcomes. It may also be the fact that relapse or lack of complete fill is only present in the larger defects as was the case in the clinical trial by Lee et al. Overall, whether or not relapse will occur is unclear at this time and longer follow-up studies are required. However, based on the direction of the findings reported above, one can speculate that once treated with HA, the clinical and subjective improvements achieved following surgery may be quite stable.

Other Applications of this New Surgical Model

A unique element of this novel surgical approach for papilla fill is the ability to combine it with restorative or even orthodontic treatment modalities. In areas of deficient papilla, the simple administration of HA has already been used with other restorative techniques. A case report demonstrated the successful use of direct composite resin with dermal filler application to close a midline diastema with an embrasure space of 1.5-2mm. Following the placement of provisional crowns to form an ideal contact point, Juvéderm® Ultra XC injections into the papilla were performed, followed by repeated injections twenty-one and forty-eight days later. At one month, about 1mm of papilla fill had been achieved, and final crowns were made to fill the remaining space. Eighteen months following treatment, complete papilla fill was still maintained. This patient was provided with an ideal esthetic result without the need for further orthodontic treatment, which would have resulted in prolonged treatment time at additional cost.

Possible Sources of Error and Opportunities for Improvement

A possible error in our clinical assessments was the use of a UNC-15mm probe to measure the distance from the contact point to the tip of the interdental papilla and rounding these measurements to the nearest half millimeter. An assessment of intra-examiner variability in periodontal probing reproducibility with the calculation of a correlation coefficient would have enabled self-calibration and reduced potential bias. However, studies assessing intra-examiner variability on periodontal probing have concluded there are no statistically significant differences
in measurement error.\textsuperscript{86} One must also consider these surgical treatments were performed by a novice clinician in a periodontal residency program. Perhaps even better outcomes might have occurred were the surgical treatments performed by a more experienced periodontist. Furthermore, our ability to accurately reproduce photographs at follow-up appointments was limited. As in previous studies by other investigators, photographs were taken in an attempt to reproduce the same horizontal and vertical distances and angulation each time.\textsuperscript{58,70,71} This has been minimized, but not eliminated, by Lee et al.\textsuperscript{61} with the introduction of a ‘photographic standardization device’ and should be considered for use in future studies. We also recommend the utilization of a controlled injection device.\textsuperscript{61} Such a device could provide for more accurate drug administration, while minimizing the volume required.
Conclusion and Future Directions

This clinical pilot study presents a unique, minimally invasive surgical approach for simultaneous treatment of deficient interdental papillae and gingival recession defects (when both are present) with minimal marginal tissue trauma and post-operative morbidity. Unlike most investigations in this area, we chose to place an emphasis on the understanding and quantification of subjective outcome measures from the perspective of both patients and clinicians. In particular, we showed that, with respect to patient-based-outcome measures, it was possible to demonstrate statistically significant improvements and even more importantly; clinically significant improvements. However, the measurement of clinical outcomes is also critically important when assessing this type of treatment intervention. It was also possible to demonstrate statistically significant improvements in these outcomes as well. Thus, the collection and objective interpretation of post-operative data, along with patient-reported outcomes, shows that this treatment modality produces predictable results that are highly valued by patients. We hope that in developing this novel surgical treatment we have laid the foundation for longer-term, more comprehensive and randomized clinical trials, to study and possibly improve this treatment approach. We hope that in the not too distant future, we will have demonstrated that this surgical method as well as our approach to evaluation of treatment outcomes an important part of the armamentarium of clinicians who treat aesthetic gingival problems.
Tables and Figures

**Table 1:** Primary VAS scores at baseline, six weeks and six months following treatment. *Patient failed to complete initial assessment. †Miller class 4 defect. ‡Tarnow class 2 and 3 defects. **Statistically significant differences (p≤0.01) in comparison to pre-treatment VAS scores.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Pre-treatment: How would you rate your papilla fill and/or root coverage?</th>
<th>6 weeks post-treatment: How would you rate your papilla fill and/or root coverage?</th>
<th>6 months post-treatment: How would you rate your papilla fill and/or root coverage?</th>
<th>∆VAS scores 6 weeks after treatment</th>
<th>∆VAS scores 6 months after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>31.37%</td>
<td>80.2%</td>
<td>92.16%</td>
<td>48.83%</td>
<td>60.79%</td>
</tr>
<tr>
<td>02*</td>
<td>N/A</td>
<td>78.22%</td>
<td>47.52%</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>03</td>
<td>6.93%</td>
<td>59.41%</td>
<td>83.16%</td>
<td>52.48%</td>
<td>76.23%</td>
</tr>
<tr>
<td>05</td>
<td>0%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>07††</td>
<td>0%</td>
<td>60.4%</td>
<td>52.41%</td>
<td>60.4%</td>
<td>52.41%</td>
</tr>
<tr>
<td>08††</td>
<td>10.78%</td>
<td>74.26%</td>
<td>60.4%</td>
<td>63.48%</td>
<td>49.62%</td>
</tr>
<tr>
<td>10</td>
<td>28.43%</td>
<td>91.09%</td>
<td>100%</td>
<td>62.66%</td>
<td>71.57%</td>
</tr>
<tr>
<td>11</td>
<td>18.63%</td>
<td>87.13%</td>
<td>100%</td>
<td>68.50%</td>
<td>81.37%</td>
</tr>
<tr>
<td>12††</td>
<td>0%</td>
<td>6.93%</td>
<td>33.66%</td>
<td>6.93%</td>
<td>33.66%</td>
</tr>
<tr>
<td>13</td>
<td>5.94%</td>
<td>68.32%</td>
<td>95.05%</td>
<td>62.38%</td>
<td>89.11%</td>
</tr>
<tr>
<td>Mean VAS scores</td>
<td>11.34%±12.15%</td>
<td>70.60%±25.84%</td>
<td>76.44%±25.40%</td>
<td>60.66%** (CI=42.05 – 79.27)</td>
<td>68.31%** (CI=52.11-84.51)</td>
</tr>
<tr>
<td>Mean VAS scores of Tarnow class 1 and/or Miller class 1 and 2 defects (7/10 cases)</td>
<td>15.22%±11.79%</td>
<td>80.62%±13.75%</td>
<td>88.27%±18.98%</td>
<td>65.81%** (CI=46.66–84.96)</td>
<td>70.60%** (CI=47.26–93.94)</td>
</tr>
</tbody>
</table>
Table 2: Secondary VAS scores one-two weeks following treatment. *Miller class 4 defect. †Tarnow class 2 and 3 defects.

<table>
<thead>
<tr>
<th>Patient</th>
<th>How would you rate your overall surgical experience? (Very good experience = 100%)</th>
<th>How would you rate your surgical experience based on pain? (Unbearable pain = 100%)</th>
<th>How would you rate your surgical experience based on tolerance of procedure? (Intolerable = 100%)</th>
<th>How would you rate your surgical experience based on post-operative recovery? (Still recovering = 100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>94.06%</td>
<td>7.92%</td>
<td>16.83%</td>
<td>49.50%</td>
</tr>
<tr>
<td>02</td>
<td>66.34%</td>
<td>74.26%</td>
<td>46.53%</td>
<td>100%</td>
</tr>
<tr>
<td>03</td>
<td>60.40%</td>
<td>44.55%</td>
<td>64.36%</td>
<td>78.18%</td>
</tr>
<tr>
<td>05</td>
<td>98.12%</td>
<td>13.86%</td>
<td>2.97%</td>
<td>10.89%</td>
</tr>
<tr>
<td>07*</td>
<td>85.12%</td>
<td>75.25%</td>
<td>2.97%</td>
<td>35.64%</td>
</tr>
<tr>
<td>08†</td>
<td>10.78%</td>
<td>45.27%</td>
<td>37.62%</td>
<td>38.61%</td>
</tr>
<tr>
<td>10</td>
<td>80.20%</td>
<td>46.50%</td>
<td>22.77%</td>
<td>30.61%</td>
</tr>
<tr>
<td>11</td>
<td>55.45%</td>
<td>55.45%</td>
<td>52.46%</td>
<td>44.55%</td>
</tr>
<tr>
<td>12†</td>
<td>98.02%</td>
<td>70.30%</td>
<td>36.63%</td>
<td>27.72%</td>
</tr>
<tr>
<td>13</td>
<td>100%</td>
<td>1.98%</td>
<td>0.99%</td>
<td>2.97%</td>
</tr>
<tr>
<td>Mean VAS</td>
<td>74.85%±27.84%</td>
<td>43.53%±27.28%</td>
<td>28.41%±22.52%</td>
<td>41.87%±29.08%</td>
</tr>
</tbody>
</table>
**Table 3:** Secondary VAS scores one-two weeks following treatment in comparison to other periodontal surgeries, *Miller class 4 defect. **Tarnow class 2 and 3 defects.*

<table>
<thead>
<tr>
<th>Patient</th>
<th>How would you rate your surgical experience in comparison to other periodontal surgeries you have had based on pain? (More pain with this procedure = 100%)</th>
<th>How would you rate your surgical experience in comparison to other periodontal surgeries you have had based on tolerance of procedure? (Better tolerance with this procedure = 100%)</th>
<th>How would you rate your surgical experience in comparison to other periodontal surgeries you have had based on post-operative recovery? (Better recovery with this procedure = 100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>02</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>03</td>
<td>68.32%</td>
<td>53.47%</td>
<td>14.86%</td>
</tr>
<tr>
<td>05</td>
<td>4.95%</td>
<td>95.05%</td>
<td>95.05%</td>
</tr>
<tr>
<td>07*m</td>
<td>21.78%</td>
<td>86.14%</td>
<td>84.16%</td>
</tr>
<tr>
<td>08*m</td>
<td>9.90%</td>
<td>78.22%</td>
<td>62.38%</td>
</tr>
<tr>
<td>10</td>
<td>15.84%</td>
<td>72.76%</td>
<td>92.08%</td>
</tr>
<tr>
<td>11</td>
<td>50.50%</td>
<td>55.45%</td>
<td>54.46%</td>
</tr>
<tr>
<td>12*</td>
<td>0%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>13</td>
<td>43.56%</td>
<td>54.46%</td>
<td>69.31%</td>
</tr>
<tr>
<td><strong>Mean VAS</strong></td>
<td><strong>26.86%±24.47%</strong></td>
<td><strong>74.44%±18.64%</strong></td>
<td><strong>71.54%±28.12%</strong></td>
</tr>
</tbody>
</table>
Table 4: Secondary VAS scores six weeks after treatment. 'Miller class 4 defect. mTarnow class 2 and 3 defects.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Are you happy with the overall aesthetics?</th>
<th>Would you consider this treatment a success?</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>90.1%</td>
<td>90.1%</td>
</tr>
<tr>
<td>02</td>
<td>76.24%</td>
<td>75.25%</td>
</tr>
<tr>
<td>03</td>
<td>75.25%</td>
<td>49.5%</td>
</tr>
<tr>
<td>05</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>07m</td>
<td>52.48%</td>
<td>49.5%</td>
</tr>
<tr>
<td>08m</td>
<td>73.27%</td>
<td>78.22%</td>
</tr>
<tr>
<td>10</td>
<td>93.7%</td>
<td>94.06%</td>
</tr>
<tr>
<td>11</td>
<td>87.13%</td>
<td>87.13%</td>
</tr>
<tr>
<td>12t</td>
<td>0%</td>
<td>4.95%</td>
</tr>
<tr>
<td>13</td>
<td>67.33%</td>
<td>66.34%</td>
</tr>
<tr>
<td>Mean VAS of all 10 cases</td>
<td>71.55%±28.73%</td>
<td>69.51%±28.59%</td>
</tr>
<tr>
<td>Mean VAS of Tarnow class 1 and/or Miller class 1 and 2 defects (7/10 cases)</td>
<td>84.25%±11.63%</td>
<td>80.34%±17.74%</td>
</tr>
</tbody>
</table>
Table 5: Secondary VAS scores six months after treatment. ¹Miller class 4 defect. ²Tarnow class 2 and 3 defects.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Are you happy with the overall aesthetics?</th>
<th>Would you consider this treatment a success?</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>85.29%</td>
<td>92.16%</td>
</tr>
<tr>
<td>02</td>
<td>48.51%</td>
<td>87.13%</td>
</tr>
<tr>
<td>03</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>05</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>07m</td>
<td>33.66%</td>
<td>49.5%</td>
</tr>
<tr>
<td>08m</td>
<td>57.43%</td>
<td>59.41%</td>
</tr>
<tr>
<td>10</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>11</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>12²</td>
<td>12.87%</td>
<td>29.70%</td>
</tr>
<tr>
<td>13</td>
<td>95.05%</td>
<td>95.05%</td>
</tr>
</tbody>
</table>

Mean VAS of all 10 cases 73.28%±32.59% 81.30%±25.59%

Mean VAS of Tarnow class 1 and/or Miller class 1 and 2 defects (7/10 cases) 89.84%±19.01% 96.33%±5.12%
Table 6: VAS scores by a periodontist (1) and periodontal residents (8) following photographic evaluation of treatment outcomes. ‘Miller class 4 defect. ”Tarnow class 2 and 3 defects.

<table>
<thead>
<tr>
<th>Periodontist/ Periodontal resident</th>
<th>Pre-treatment: How would you rate this papilla fill and/or root coverage? (mean VAS of all 10 cases)</th>
<th>6 months post-treatment: How would you rate this papilla fill and/or root coverage? (mean VAS of all 10 cases)</th>
<th>ΔVAS scores 6 months after treatment: How would you rate this papilla fill and/or root coverage?</th>
<th>6 months post-treatment: Would you consider this treatment a success?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>35.1%</td>
<td>65.0%</td>
<td>29.9%</td>
<td>63.9%</td>
</tr>
<tr>
<td>2</td>
<td>30%</td>
<td>57.5%</td>
<td>27.5%</td>
<td>60.1%</td>
</tr>
<tr>
<td>3</td>
<td>44.2%</td>
<td>71.2%</td>
<td>27.0%</td>
<td>76.6%</td>
</tr>
<tr>
<td>4</td>
<td>40.8%</td>
<td>65.3%</td>
<td>24.5%</td>
<td>73.7%</td>
</tr>
<tr>
<td>5</td>
<td>60.6%</td>
<td>77%</td>
<td>16.4%</td>
<td>80.2%</td>
</tr>
<tr>
<td>6</td>
<td>33%</td>
<td>55.2%</td>
<td>22.2%</td>
<td>64.4%</td>
</tr>
<tr>
<td>7</td>
<td>34.5%</td>
<td>61.7%</td>
<td>27.2%</td>
<td>62.5%</td>
</tr>
<tr>
<td>8</td>
<td>28.1%</td>
<td>62.3%</td>
<td>34.2%</td>
<td>64.8%</td>
</tr>
<tr>
<td>9</td>
<td>19.9%</td>
<td>57.4%</td>
<td>37.5%</td>
<td>65.74%</td>
</tr>
<tr>
<td>Mean VAS</td>
<td>36.2%±11.5%</td>
<td>63.6%±7.01%</td>
<td>27.38%±6.24%</td>
<td>68.0%±7.01%</td>
</tr>
</tbody>
</table>
Table 7: Papilla fill at baseline, six weeks after treatment and six months after treatment. 'Miller class 4 defect. *Tarnow class 2 and 3 defects. *Statistically significant differences (p≤0.01) in comparison to pre-treatment VAS outcomes.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Papilla between teeth</th>
<th>Papilla defect</th>
<th>Papilla defect 6 weeks post-treatment (mm)</th>
<th>Papilla defect 6 months post-treatment (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>21/22</td>
<td>2</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>01</td>
<td>22/23</td>
<td>1</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>02</td>
<td>13/14</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>03</td>
<td>21/22</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>03</td>
<td>13/14</td>
<td>1</td>
<td>1.5</td>
<td>0.5</td>
</tr>
<tr>
<td>03</td>
<td>14/15</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>03</td>
<td>15/16</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>05</td>
<td>13/14</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>05</td>
<td>12/13</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
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<td>11/12</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>05</td>
<td>11/21</td>
<td>1</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>05</td>
<td>21/22</td>
<td>2</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>05</td>
<td>22/23</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>05</td>
<td>23/24</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>07₉</td>
<td>11/12</td>
<td>4</td>
<td>1.5</td>
<td>2</td>
</tr>
<tr>
<td>08₉</td>
<td>21/22</td>
<td>5.5</td>
<td>4</td>
<td>3.5</td>
</tr>
<tr>
<td>10</td>
<td>11/21</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>12/13</td>
<td>3</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>11</td>
<td>11/12</td>
<td>3.5</td>
<td>0.5</td>
<td>1</td>
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<tr>
<td>11</td>
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<td>3</td>
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<td>0.5</td>
</tr>
<tr>
<td>11</td>
<td>22/23</td>
<td>2</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>12₉</td>
<td>11/12</td>
<td>1.5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>12₉</td>
<td>21/11</td>
<td>1.5</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>13</td>
<td>21/22</td>
<td>3</td>
<td>0.5</td>
<td>1.5</td>
</tr>
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<td>13</td>
<td>22/23</td>
<td>2</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>13</td>
<td>12/13</td>
<td>1</td>
<td>1.5</td>
<td>1</td>
</tr>
</tbody>
</table>

Mean papilla fill

*1.3mm±0.8mm (61.24%±39.26%)  *1.3mm±0.7mm (61.84%±26.71%)
Table 8: Root coverage at initial examination and six months after treatment. \(^{5}\)Miller class 4 defect.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Teeth/Recessions (DB,B,MB for Q1 and MB,B,DB for Q2 in mm)</th>
<th>Recession 6 months post-treatment (DB,B,MB for Q1 and MB,B,DB for Q2 in mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>12 (0,1,0)</td>
<td>0,0,0</td>
</tr>
<tr>
<td>01</td>
<td>11 (0,1,0)</td>
<td>0,1,0</td>
</tr>
<tr>
<td>01</td>
<td>21 (0,2,0)</td>
<td>0,1,0</td>
</tr>
<tr>
<td>01</td>
<td>22 (1,2,1)</td>
<td>0,1,0</td>
</tr>
<tr>
<td>01</td>
<td>23 (1,2,0)</td>
<td>1,1,0</td>
</tr>
<tr>
<td>02</td>
<td>14 (0,3,0)</td>
<td>0,1,0</td>
</tr>
<tr>
<td>02</td>
<td>13 (0,4,0)</td>
<td>0,2,0</td>
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<tr>
<td>02</td>
<td>12 (0,1,0)</td>
<td>0,1,0</td>
</tr>
<tr>
<td>03</td>
<td>13 (0,1,0)</td>
<td>0,0,0</td>
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<tr>
<td>03</td>
<td>15 (1,2,1)</td>
<td>1,2,1</td>
</tr>
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<td>Mean Root coverage</td>
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<td>60.38%±43.27%</td>
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**Figure 1** Illustration of classification of papilla defects first described by Nordland and Tarnow in 1998. 

![Illustration of papilla classification](image)

**Figure 2** Juvéderm® and Emdogain® used for clinical treatment.
1) Root planing of the exposed root surfaces is performed. A 3-5 mm horizontal incision is made in the alveolar mucosa at a minimum of 2 mm beyond the mucogingival junction.

2-3) Through this access incision the periosteum is released towards the area of recession and under the deficient interdental papilla(e) (interdental papilla remains intact).

4) Juvéderm is administered into the papilla(e) to achieve ideal papillary fill. Straumann PrefGel® is used to condition the exposed cementum followed by placement of EMD and coronal repositioning of the gingiva and alveolar mucosa over the area of recession.

5) Histoacryl® is used to seal free gingival margins surrounding the papilla(e) (not used if treating papilla(e) defects in combination with recession). A sling suture is placed to maintain coronal advancement with 6.0 polypropylene. Additional injections with Juvéderm into the interdental papilla(e) are performed as needed.
**Figure 4**) Six month postoperative outcomes in the treatment of isolated papilla defects and gingival recession in combination with papilla deficiencies.

**Case 03**

**Preoperative**

**Six months postoperative**

**Case 05**

**Preoperative**

**Six months postoperative**
Case 11

Preoperative

Six months postoperative
Case 13

Preoperative

Six months postoperative
Appendices

Appendix A: Medical Questionnaire

Medical Questionnaire
University of Toronto
Faculty of Dentistry

For office use only: Date:
- Perio
- Surgery
- Endo
- Crown
- Bridge
- Amal/Resin
- P/Dent
- F/Dent
- Implants
- Other
- C/O 1-2-3-4
- MHO

Comments:

Radiographs: Pt to obtain x-rays; reassess
- FMS
- Pan
- Special procedures
- Pan + B/W
- Pan + selected periapicals
- Other

Screening signature:

Have you ever been a patient at this Faculty? Yes ______ No ______

To provide the best possible care for our patients, all patients must fill out this questionnaire completely.
Please answer the following questions as accurately as possible. If you have any questions or doubts, please check (✓) the "Not sure/ Maybe" choice.

1. Are you being treated for any medical condition at the present or have you been treated within the past year? If so, why? ________________________________

2. Was your last medical check-up within the past one year? ________________________________

3. Has there been any change in your general health in the past year? ________________________________

4. Are you taking any medications or non-prescription drugs of any kind? ________________________________
   If YES, LIST ________________________________

5. Do you have any allergies? (e.g. Hayfever, Latex/Rubber) ________________________________

6. Have you ever had peculiar or adverse reaction to any medicines or injections? (e.g. penicillin, aspirin, local anaesthetics, "dental freezing") ________________________________

7. Do you have or have you ever had any of the following? Please check off (✓) all that apply.
   - Heart murmur
   - Heart transplant
   - Heart surgery
   - Artificial heart valve
   - Infection of the heart (endocarditis)
   - Shortness of breath
   - Heart failure
   - Blood pressure problem
   - Rheumatic fever
   - Mitral valve problems
   - Congenital heart disease (from birth or early childhood)
   - None of the above

8. Do you have any condition that could affect your immune system, e.g. Leukemia, AIDS, HIV infection? ________________________________

9. Do you have any tendency to bruise easily or bleed for a prolonged period of time after a cut? ________________________________

10. Have you ever been hospitalized for any illnesses or operations? ________________________________
    Please explain: ________________________________
11. Do you have, or have you ever had, any of the following? Please check off (✓) all that apply.

- Hepatitis
- Lung disease
- Steroid therapy
- Arthritis, type
- Jaundice
- Tuberculosis
- Diabetes
- Seizures
- Liver disease
- Asthma
- Kidney disease
- Bone strengthening pills (e.g., Fosamax, Actonel)
- Stomach ulcers
- Cancer
- Prosthetic joint

(How long) 

12. Are there any conditions or diseases not listed above that you have or have had? 

13. Are there any diseases or medical problems that run in your family? (e.g., diabetes, cancer or heart disease?) 

14. Do you or did you smoke? If so, how much? 

15. Do you drink alcoholic beverages on a regular basis? 

16. Do you use recreational drugs (such as cocaine or amphetamines)? 

17. Are you nervous during dental treatment? 

18. How nervous are you? (Indicate by marking the scale below). 

NOT AT ALL - 1 2 3 4 5 VERY ANXIOUS 

19. If you are nervous, would you like us to consider additional techniques, along with "freezing", to help you? 

20. Have you ever had any serious trouble with any previous dental treatment? 

21. For women only, are you pregnant? 

If so, what is the expected delivery date? 

<table>
<thead>
<tr>
<th>Date</th>
<th>Diagnosis Appointment</th>
<th>Staff Signature</th>
<th>Student Signature</th>
<th>Emergency Appointment</th>
</tr>
</thead>
</table>

CONSENT FORM: I ACKNOWLEDGE that the information given above is true to the best of my knowledge and that the questions have been reviewed with me. Should there be any change to my present health status in the future, I will advise the Faculty. I have been informed that my physician may be contacted by letter, fax or telephone in order to complete details of my medical history. I hereby consent to my physician providing the Faculty of Dentistry, University of Toronto with any information in this regard which may help ensure safe dental treatment. Finally, I hereby acknowledge that dental treatment may be delayed until all medical information required by the Faculty of Dentistry is received.

Date: ___________________ Patient Signature: ___________________ Witness Signature: ___________________

Medical Doctor's Name: ___________________ Medical Doctor's Phone #: ___________________

Medical Doctor's Address: ___________________

Specialist Doctor's Name: ___________________ Specialist Doctor's Phone #: ___________________

Specialist Doctor's Address: ___________________
Appendix B: Consent Meeting Script/Interview Guide

CONSENT MEETING SCRIPT FOR RESEARCH PARTICIPANTS
AT THE UNIVERSITY OF TORONTO

Individuals who wish to participate and are selected for the clinical trial will be asked to sign an informed consent (see appendix E). A sample consent meeting script has been provided below to help simulate the process in which informed consent will be obtained.

Examiner: Welcome, my name is Dr. Stephen Spano and I am a graduate periodontics resident here in the Graduate Program in Periodontology, within the Faculty of Dentistry, University of Toronto. You have been selected to be a potential participant in a clinical trial that I am conducting in the graduate periodontics clinic for my Masters’ project. With your permission, I would like to inform you of the trial in detail. You can stop me at any point if you have any questions.

The purpose of our experiment is to provide patients with the option of restoring the original position of their receding gums below and/or in between their teeth through a new conservative surgical technique we have developed. It is our intent that this novel minimally invasive surgery will provide you with effective treatment results in addition to minimal discomfort and optimal healing time. It is also our hope this study will allow for an effective treatment alternative for future clinicians to provide to their patients. Questions so far?

Participant: Can you please explain further the treatment I will be receiving?

Examiner: Of course I can. This treatment will be based on a minor surgical procedure that creates a tiny hole in your gums in the area of your gum defect followed by the placement of a natural based dermal filler called Juvéderm® as well as a protein factor called Emdogain®. Dermal fillers are materials composed of a natural protein and sugar compound found in human skin. They have been used extensively in medicine for procedures involving lip augmentation as well as elimination of facial folds, facial wrinkling and undesirable facial lines. Emdogain® is a natural material that enhances the regeneration of your gums and will be placed over the exposed root surfaces in areas where you have recession. It also assists in post-operative healing and minimizes patient’s recovery time. Through the use of these two materials we hope to achieve root coverage and fill papilla deficiencies. Root coverage is defined as the restoration of the receded gums to their original position over the entire root surface. Papilla deficiencies are spaces that occur between teeth as a result of receding gums. Following the insertion of the dermal filler and Emdogain, stitches will be placed to hold the tissues and material in position during healing. We will then follow you closely over a 6-month period to evaluate the success of the surgical procedure.

Participant: Is this surgery required?

Examiner: It is always your choice whether you wish to proceed with treatment or not. The main reasons for undergoing this procedure are to improve the aesthetics of the gingival tissues around your teeth and in some cases of where your roots may be exposed, for the management of dentinal hypersensitivity. It is our hope that this surgery will address both these issues by providing root coverage (restore the gums that have receded and exposed the roots of your teeth) and/or papilla regeneration (restore the position of the gums in between your teeth).
Participant: What other options do I have?
Examiner: Unfortunately, there is currently no predictable way to recreate the gums between your teeth to fill papilla deficiencies. However, there are a variety of different treatments available for receding gums. These techniques can be very invasive and painful. Further, the most predictable treatment options require two separate surgical sites (one for the recipient site and one on the roof of your mouth to obtain tissue to place over the site with the defect). As previously stated, with our treatment we would not have to obtain additional tissue from the roof of your mouth, significantly decreasing post-operative pain. All alternative treatment options are highlighted below. In different situations some treatment options are better than others. All involve similar risks and sequelae. This includes pain, bruising, bleeding, swelling, infection, temporary or permanent dental sensitivity to heat or cold and treatment failure. During your treatment at the Faculty of Dentistry you will be provided with contact information for any questions or emergencies and routine post-operative appointments to follow-up and confirm the site is healing accordingly.

Treatment options for gum recession

1. Gum graft – this involves taking tissue from the roof of your mouth and is the standard procedure for the treatment of gum recession
   a. Advantages
   - Most predictable surgery for root coverage
   b. Disadvantages
   - Requires a donor site (second surgical site) to obtain the gum tissue
2. Moving of your remaining gums in the area over the exposed root surface
   a. Advantages
   - Only one surgical site
   b. Disadvantages
   - Can only be performed in specific circumstances
   - No new gum tissue provided
3. Gum from a “bottle”
   a. Advantages
   - Only one surgical site
   b. Disadvantages
   - Unpredictable long term root coverage
   - Donated human tissue
4. No treatment
   a. Advantages
   - No surgery
   b. Disadvantages
   - Recession likely to progress
   - Ongoing and/or worsening dental sensitivity
   - Chronic inflammation

Participant: Are dermal fillers safe?
Examiner: The dermal filler we will be using is a very safe material. The Food and Drug Administration in the USA as well as the regulatory factions in Canada have approved the use
and safety of dermal fillers for over a decade. The utilization of dermal fillers in plastic surgery and dermatology is now a very common, effective and long-standing therapeutic modality for treatment of a variety of different aesthetic problems related to the skin. There have also been studies to prove their compatibility inside the mouth.

Participant: What if I do not want to participate. Will this affect my current treatment here?
Examiner: Not at all! There will be no consequences if you choose not to participate or if you agree to participate and change your mind later on. The quality of your care here at the Faculty of Dentistry, University of Toronto, will not be affected by your decision.

Participant: How many appointments will be required of me?
Examiner: Including today, you will require another appointment for the surgery and 3 to 4 follow-up appointments. The surgical appointment will be about an hour and the follow-up appointments will range from 15-45 minutes. At some of these follow-up appointments we will be taking photographs and will be asking you to complete simple questionnaires regarding your surgical experience.

Participant: Will I get anything for participating aside from the surgery?
Examiner: Unfortunately, there is no monetary compensation for participating in the study. The treatment of the surgical site will be free of charge including any required follow-up appointments. There will be a $100.00 fee charged to the patient prior to treatment. This will be reimbursed in full at the 6-month follow-up after treatment. If you drop out of the study prior to completion no compensation will be provided. Furthermore, due to the limited finances provided for this study, no compensation can be provided in the event of a personal injury or unexpected complication that forces the participant to withdraw from the study. You will also be shown proper oral hygiene techniques and provided with free oral hygiene supplies.

Participant: What guarantee do I have that this treatment will work?
Examiner: Unfortunately, this new treatment that has never been attempted before. There is no research on the success rates for this type of therapy. However, the clinical protocol and approach we have developed has been reviewed and is based on sound periodontal principles and surgical techniques. Nonetheless, it is important to keep in mind that this is an innovative surgical technique and I cannot guarantee it will be successful. If treatment does fail, the condition becomes worse, or if you develop a complication such as an infection, the cost of additional treatment or medication through the Faculty of Dentistry or an outside clinic will not be covered. It is very unlikely that the condition worsens post-surgery. The risk for this is minimal and would be equal to that of any type of root coverage procedure whether or not dermal filler is used. In fact, on the basis of our understanding relating to how these treatments work, it is highly probable in our opinion that there will actually be reduced risk for worsening of a patient’s condition.

Participant: How much is this going to hurt and how long will it take me to recover?
Examiner: This is a very minor surgical procedure. It is much less invasive and traumatic than a tooth extraction. If you have had any previous gum grafting surgery this would likely be less uncomfortable than that as well. However, everyone responds differently to surgery and post-operative pain. You will be followed up with carefully to confirm normal healing and for the management of any post-op complications that may arise. As with all dental surgeries patients
may experience some post-operative discomfort, bruising, swelling and bleeding. Post-operative instructions will be reviewed in detail with you to minimize any of these potential complications. An emergency contact number will be provided as well.

**Participant:** Who will have access to my personal information?

**Examiner:** Participant’s records and consent forms will be kept in locked filing cabinets at the University of Toronto’s dental clinic. Only myself and the other investigators in this study will have access to your information. Photographs will be immediately erased from the digital camera and computer the day of and stored on an encryption protected USB flash drive. All electronic information will be saved and stored on the encryption protected USB flash drive as well. This information will be uploaded and analyzed only on computers linked to the Faculty of Dentistry’s secured server. However, the information will only be stored on the USB memory device and not on the computer server. The USB memory device will be kept in a locked desk drawer in a locked room.

**Participant:** That’s all the questions I have for now. I would be interested in participating. However, are you available if I have any other questions?

**Examiner:** I will now be handing you an information letter (see *appendix C*) that includes all the things we just spoke about. As you look through them, feel free to contact me if you have any further questions.

**Participant:** Thank you Dr. Spano.

**Examiner:** You are very welcome. At this time do you have any questions regarding the trial? Do you have any questions regarding what we expect from the participants in the trial? Do you have any questions regarding your option not to participate?

**Participant:** No, you explained everything quite clearly.

**Examiner:** Great! I will now ask you to take your time and read through this consent form (see *appendix D*). If you are okay with everything it outlines please sign where indicated. I will keep this in your chart. If you wish, you can have a copy of the signed consent form as well. Please keep in mind the next appointment will be for your surgery. Here is some post-operative instructions you can review that will be important for you to follow after treatment. I will provide you with the same instructions on the day of the surgery as well.
Appendix C: Information Letter for Research Participants

INFORMATION LETTER FOR RESEARCH PARTICIPANTS 
AT THE UNIVERSITY OF TORONTO

Title of research project: The use of dermal filler in root coverage and the restoration of papilla deficiencies through a conservative surgical approach

Introduction
Thank you for considering taking part in our research. This is a Masters research project being conducted by the periodontal resident Dr. Stephen Spano in the Graduate Program in Periodontology, within the Faculty of Dentistry, University of Toronto. The information below will help explain our study, the treatment you will be electing to receive and the associated risks and benefits to you. It is up to you to decide whether you would like to participate in the clinical trial. Please make sure that all of your questions are answered before you provide consent.

Background
Healthy gums are the foundation to optimal oral health and are very important in the overall aesthetics of your teeth. Abnormal brushing techniques or gum disease can cause a loss or a change in the appearance of your gums. Many patients have receding gums exposing the roots of their teeth and the spaces between their teeth. This can cause outstanding grief due to the resultant unpleasant appearance and increased tooth sensitivity. These spaces that occur between the teeth as a result of gum recession are called papilla deficiencies. Treatment that involves the use of a material to cover the exposed root surface and restore the original position of the receded gums is termed root coverage. Unfortunately, patients frequently undergo multiple invasive surgeries to obtain root coverage and fix papilla deficiencies that require extensive healing time. Furthermore, in many cases no predictable treatment is even available. Thus, using a new conservative surgical technique we have developed, it is our intent to provide you with a minimally invasive surgical procedure with little discomfort, optimal healing time and effective results.

Purpose of the Research:
The purpose of our research is to provide patients with the option to restore the original position of their receding gums through a new conservative surgical technique. It is ultimately our hope this study will allow for an effective treatment alternative for future clinicians to provide to their patients. This treatment will consist of making a tiny hole in your gums and placing dermal filler underneath them to bulk up and fill the gums around your teeth. These dermal fillers are biodegradable materials composed of a natural complex of protein and sugar found in human skin. They have been used extensively in medicine for procedures involving lip augmentation as well as eliminating facial folds, facial wrinkling and undesirable facial lines. The dermal filler we will be using is called Juvéderm® and is a very safe material. Previous studies have shown mild success in using dermal fillers in restoring the natural appearance of gums and it is our hope that our advanced method in dermal filler placement will allow for even greater improvements in root coverage and gum restoration.
**Description of the Research:**
This research clinical plot trial will be composed of about 15 patients from the graduate periodontics clinic. Patients will be selected on a wide range of medical and clinical criteria. Those who are acceptable candidates will be asked to return and participate in the study. Following surgery we will follow you closely over a 6-month period to evaluate the success of the treatment.

**Participants' Duties**
Participants will undergo an initial examination, surgery and multiple follow-up appointments. Please review the information below for a detailed explanation of each appointment:

**Appointment 1) – 45-60 minutes**
- Review of medical history, initial oral examination, informed consent, and pre-operative photographs. Following an initial examination at the Faculty of Dentistry, patients that meet the inclusion criteria will be invited back to participate in the study and asked to complete some quick pre-operative assessments.

**Appointment 2) - 120 minutes**
- Patient’s undergo minor surgery to restore area of receding gums. This includes the administration of dental freezing, incision of the gums and placement of the dermal filler. Patients will also receive a few stitches in the area to hold the gums and materials in place during the healing process. A thorough review of post-operative instructions verbally and written will be provided.

**Appointment 3) – 30 minutes**
- A 1-week follow-up will be scheduled to assess healing of surgical site and review oral hygiene as well as any patient questions or concerns. Patients will be asked to complete some post-operative assessments. Post-operative measurements and photographs will be taken.

**Appointment 4) – 30 minutes**
- 6-week follow-up to assess healing, review oral hygiene and address patient questions or concerns. Data will be collected through photography and specific assessments the participants will be asked to complete. Several different clinical measurements will be taken of the gums and teeth in the treated area.

**Appointment 5) – 30 minutes**
- 6-month follow-up to assess healing, review oral hygiene and address patient questions or concerns. Data will be collected through photography and specific assessments the participants must complete. Several different clinical measurements will be taken of the gums and teeth in the treatment area.

**Appointment 6)**
- Patients may be asked for an additional appointment to complete any outstanding clinical assessments.
Potential Harms or Injuries:
This is a minor surgical procedure. As with all dental surgeries patients may experience some post-operative discomfort, bruising, swelling and bleeding. Post-operative instructions will be reviewed in detail to minimize any of these potential complications. An emergency contact number will also be provided. The Food and Drug Administration in the USA as well as the regulatory factions in Canada have approved the use and safety of dermal fillers for over a decade. Further, the utilization of dermal fillers in plastic surgery and dermatology is now a very common, effective and long-standing therapeutic modality for treatment of a variety of different aesthetic problems related to the skin. There have also been studies to prove their compatibility inside the mouth. It is important to understand that this is an innovative surgical technique that has never been tested before. However, the clinical protocol and approach we have developed has been reviewed and is simply a modification of current and sound periodontal principles and surgical techniques. Considering dermal fillers do degrade over time please understand it will be impossible to obtain long-term stability. However, if significant results are obtained this may allow for an effective treatment alternative for clinicians and patients that we estimate would require simple and much less invasive ongoing 2-3-year maintenance visits to essentially “touch-up” the affected area(s).

Confidentiality:
All personal information including participants’ records, consent forms and questionnaires will be kept in the patient’s dental chart at the Faculty of Dentistry. Photographs will be immediately erased from the digital camera and computer and stored on an encryption protected USB flash drive. All electronic information will be saved and stored on the encryption protected USB flash drive as well. This information will be uploaded and analyzed only on computers linked to the Faculty of Dentistry’s secured server. However, the information will be stored only on the USB memory device and not on the computer server. The USB memory device will be kept in a locked desk drawer in a locked room. We will not release or publish any information that reveals the participants' identity. All patient identifying information will be removed during clinician and participant assessments of pre- and post-operative photographed treatment results. All personal records obtained will be securely stored for 25 years and then shredded and erased.

Participation and Compensation:
Participation in this study is voluntary and no monetary compensation will be offered. However, other forms of compensation include:

1) All examinations, treatment and follow-up appointments will be free of charge.
2) Proper oral hygiene instruction and free oral hygiene supplies will be given to all participants.
3) There will be a $100.00 fee charged to the patient prior to treatment. This will be reimbursed in full at the 6-month follow-up after treatment. If you drop out of the study prior to completion no compensation will be provided.

Participation in this study may contribute to the development of new treatments or other events that may have commercial value. Your participation will not entitle you or other trial participants to a share in any future economic benefits. Furthermore, due the limited finances provided for this study, no compensation can be provided in the event of a personal injury or unexpected complication that forces the participant to withdraw from the study. If treatment does fail, the condition becomes worse, or if you develop a complication such as an infection, the cost of additional treatment or medication through the Faculty of Dentistry or an outside clinic will not be covered. However, it is very unlikely that the condition worsens post-surgery.
The risk for this is minimal and equal to that of any root coverage procedure whether or not dermal filler is used. In fact, on the basis of our understanding relating to how these treatments work, it is highly probable in our opinion that there will actually be reduced risk for worsening of a patient’s condition.

**Withdrawal**
Participants who are not interested in undergoing treatment are not obliged to continue with the study and can leave at any time. We strongly encourage you to consider this prior to undergoing surgery. However, patients must understand that once treatment is provided we highly recommend attending all follow-up appointments to confirm the site of surgery is healing normally and ask you kindly to complete the simple post-operative assessments we will be requesting from you.
Appendix D: Eligibility Screening Consent Form

ELIGIBILITY SCREENING CONSENT FORM FOR PATIENTS
AT THE UNIVERSITY OF TORONTO

The use of dermal filler in root coverage and the restoration of papilla deficiencies through a conservative surgical approach

Eligibility Consent:

1) The study has been explained to me and I am aware this research is part of a Masters project. This Masters research project is being conducted by the periodontal resident Dr. Stephen Spano in the Graduate Program in Periodontology, within the Faculty of Dentistry, University of Toronto.

2) I understand that I have the right not to participate and the right to stop at any time. The decision about whether or not to participate will not affect my other dental care at the Faculty of Dentistry.

3) I understand and accept that by signing this form I am only providing consent for a consultation that will involve further discussion with Dr. Spano of his research and the completion of medical and research questionnaire forms. I am also providing consent for a detailed clinical examination of the status of my teeth and gums as well as intra-oral photographs.

4) At this appointment I understand I am not committed to undergoing any treatment proposed by Dr. Spano.

5) I realize that I am free now, and in the future, to ask any questions or request further consultations about the research study. The costs involved in obtaining a consult or second opinion regarding the treatment required outside of the Faculty of Dentistry will not be covered.

6) I am aware that researchers will use data from my dental chart, including demographics, a detailed medical history, social history and periodontal status and diagnosis. I understand photographs will also be taken and that all data obtained will be used for research purposes only. I recognize that no information that would identify me will be released or printed. I understand that some of the information collected may be used in hopes of publication or public presentations even if I do not proceed with treatment and that my personal information will remain protected. I agree to release and exchange of my dental/medical information between the investigators of this study only.

7) I was given the opportunity to ask questions and my questions have been answered to my satisfaction. I have been provided with adequate information and wish to be screened for eligibility for this research study.

I, ____________________ (Participant), hereby consent to participate. Date: __________

Signature: ____________________
Name of person who obtained consent __________________________ Date: ____________

Signature of person who obtained consent __________________________ Date: ____________
Appendix E: Treatment Consent Form

TREATMENT CONSENT FORM FOR PATIENTS
AT THE UNIVERSITY OF TORONTO
The use of dermal filler in root coverage and the restoration of papilla deficiencies through a conservative surgical approach

Consent:
By signing this form:

1) The study has been explained to me and I am aware this research is part of a Masters project. This Masters research project is being conducted by the periodontal resident Dr. Stephen Spano in the Graduate Program in Periodontology, within the Faculty of Dentistry, University of Toronto.

2) I understand that I have the right not to participate and the right to stop at any time during the research study. I am under no obligation to participate and free to withdraw without any consequences. Further, the decision about whether or not to participate will not affect any other dental care I may have at the Faculty of Dentistry.

3) I realize that I am free now, and in the future, to ask any questions about the study. The costs involved in obtaining a consult or second opinion regarding the treatment required outside of the Faculty of Dentistry will not be covered.

4) I understand the written and verbal information provided to me by Dr. Spano. The normal course of treatment, expected outcomes, associated risks and complications have been thoroughly explained to me. The nature and purpose of the treatment, possible treatment alternatives with their associated benefits and risks, and the potential complications have been thoroughly explained to me in a manner that I understand. I am aware the risks and complications resulting from this procedure may include but are not limited to:
   • Pain, bruising, swelling, bleeding and infection
   • Damage to adjacent teeth, fillings or other dental restorations
   • Treatment failure
   • Teeth may become temporarily or permanently sensitive to heat, cold or sweets
   • Several days of at-home recovery may be required

5) I recognize it is essential for me to follow all the post-operative instructions highlighted below after my surgery:
   • No rinsing, spitting or drinking with a straw for 24 hours to prevent bleeding.
   • Pain and swelling: Pain and occasional swelling may occur and is normal. Pain peaks after a few days and can persist for one week. Pain is normally managed with acetaminophen (Tylenol®) and/or ibuprofen (Advil®). Only use the pain medication as needed and instructed by the clinician.
     Note: It is normal when the dental freezing wears off to have some additional discomfort. Use the pain medication as needed to help manage the increase in pain at this time.
   • Bleeding: A small amount of bleeding is normal. If there is considerable bleeding do not spit or rinse repeatedly. Very gently take a piece of sterile gauze or tea bag and hold it over the area for 20-30 minutes (do not talk or release the pressure). If the bleeding persists contact the office.
   • Mouth Rinses: You will be provided with a germ killing mouth rinse called chlorhexidine to reduce the risk of post-operative infection. Begin rinsing the day after surgery as instructed. Do not rinse the first day of surgery as this can cause additional bleeding.
   • Brushing: Maintaining good oral hygiene will minimize the risk of infection. Provided there is no bleeding resume gentle brushing of all areas except the site of surgery the following day. Avoid
brushing over the surgical site for 3-5 days, then brush very gently after meals to remove any food debris that accumulates. Normal brushing can resume 2 weeks following surgery.

- **Antibiotics:** An antibiotic is normally not required. If prescribed, finish it all as directed.
- **Sutures:** Sutures have been placed and will dissolve on their own in 7-14 days. Do not touch or play with the sutures.
- **Smoking:** No smoking of any kind should take place for two weeks following surgery.
- **Diet:** A soft diet is recommended for the first 5 days (mashed potatoes, soups, yogurt, etc.) following surgery. Normal diet can usually resume in one week.
- **Infection:** If the site becomes very swollen, extremely painful with or without a bad taste call the periodontal office.

6) I accept, understand and agree to follow the instructions provided to me before and after the procedure.

7) Due the limited finances provided for this study, I recognize that in the event of a personal injury or unexpected complication that forces me to withdraw from the study no compensation can be provided. I also understand there is a $100.00 fee prior to treatment. This is reimbursed in full at the 6-month follow-up after treatment.

8) I understand if treatment fails, the cost of additional treatment through the Faculty of Dentistry or an outside clinic will not be covered.

9) By consenting to treatment I have not waived any rights to legal recourse in the event of research-related harm.

10) I was given the opportunity to ask questions and my questions have been answered to my satisfaction. I have been provided with adequate information and wish to proceed with treatment.

I, __________________________ (Participant), hereby consent to participate. Date: ______________

Signature: ________________________

Participants’ data collection

1) I am aware that researchers will use data from my dental chart, including demographics, a detailed medical history, social history and periodontal status and diagnosis. I understand photographs and/or video will also be taken and that all data obtained will be used for research purposes only. I recognize that no information that would identify me will be released or printed. I understand that some of the information collected may be used in hopes of publication or public presentations and that my personal information will remain protected. I agree to release and exchange of my dental/medical information between the investigators of this study only.

Signature: ________________________

Name of person who obtained consent __________________________ Date: ______________

Signature of person who obtained consent __________________________ Date: ______________
Appendix F: Postoperative Instructions

Instructions Following Surgery

1. **No rinsing, spitting or drinking with a straw for 24 hours** to prevent bleeding.
2. **Pain and swelling:** Pain and occasional swelling may occur and is normal. Pain peaks after a few days and can persist for one week. Pain is normally managed with acetaminophen (Tylenol®) and/or ibuprofen (Advil®). Only use the pain medication as needed and instructed by the clinician.
   
   **Note:** It is normal when the dental freezing wears off to have some additional discomfort. Use the pain medication as needed to help manage the increase in pain at this time.
3. **Bleeding:** A small amount of bleeding is normal. If there is considerable bleeding **do not spit or rinse repeatedly.** Very gently take a piece of sterile gauze or tea bag and hold it over the area for 20-30 minutes (do not talk or release the pressure). If the bleeding persists contact the office.
4. **Mouth Rinses:** You will be provided with a germ killing mouth rinse called chlorhexidine to reduce the risk of post-operative infection. Begin rinsing the day after surgery as instructed. Do not rinse the first day of surgery as this can cause additional bleeding.
5. **Brushing:** Maintaining good oral hygiene will minimize the risk of infection. Provided there is no bleeding resume gentle brushing of all areas except the site of surgery the following day. Avoid brushing over the surgical site for 3-5 days, then brush very gently after meals to remove any food debris that accumulates. Normal brushing can resume 2 weeks following surgery.
6. **Antibiotics:** An antibiotic is normally not required. If prescribed, finish it all as directed.
7. **Sutures:** Sutures have been placed and will dissolve on their own in 7-14 days. Do not touch or play with the sutures.
8. **Smoking:** No smoking of any kind should take place for two weeks following surgery.
9. **Diet:** A soft diet is recommended for the first 5 days (mashed potatoes, soups, yogurt, etc.) following surgery. Normal diet can usually resume in one week.
10. **Infection:** If the site becomes very swollen, extremely painful with or without a bad taste call the periodontal office.

For emergencies call our periodontal office
Appendix G: Case Report Form

CASE REPORT FORM

Clinical Pilot Trial:
The use of dermal filler in root coverage and the restoration of papilla deficiencies through a conservative surgical approach

Investigator: Dr. Stephen Spano

Case # [__][__]
SCREENING VISIT
(Initial Consultation and Assessment)

Date of Visit:  __ __ __ __ __ __ __ __ __ __
                   Day / Month / Year

Written Informed Consent:

Date obtained: __ __ __ __ __ __ __ __ __ __
                   (Day / Month / Year)

Demographic Details: Year of Birth: __ __ __ __ __ __ __ __
Sex: Male ___
          Female ___

Inclusion Criteria

- Over 18 years of age: Yes No
- Informed consent obtained. Patient is willing to proceed with all treatment and follow-up appointments: Yes No
- Presence of localized areas of recession and/or interdental papilla loss: Yes No
- No contraindications to periodontal surgery: Yes No

Exclusion criteria

- Active periodontal disease: Yes No
- Presence of gingivitis in the proposed surgical area: Yes No
- Pregnant: Yes No
- American Society of Anaesthesiologists’ physical status classification of 3 or greater: Yes No
- Smokers or patients with a history of smoking in the past 10 years: Yes No
Recession and/or Papilla Defects

<table>
<thead>
<tr>
<th>Recession</th>
<th>Yes</th>
<th>No</th>
<th>Class 1 Teeth:</th>
<th>Class 2 Teeth:</th>
<th>Class 3 Teeth:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papilla Deficiencies</td>
<td>Yes</td>
<td>No</td>
<td>Class 1 Teeth:</td>
<td>Class 2 Teeth:</td>
<td></td>
</tr>
<tr>
<td>Recessions with Papilla</td>
<td>Yes</td>
<td>No</td>
<td>Teeth:</td>
<td>Teeth:</td>
<td></td>
</tr>
<tr>
<td>Deficiencies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pre-Operative Clinical Measurements

<table>
<thead>
<tr>
<th>Measurement</th>
<th>mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical attachment loss (CAL)</td>
<td></td>
</tr>
<tr>
<td>Recession from cemento-enamel junction (CEJ) to free gingival margin (FGM)</td>
<td></td>
</tr>
<tr>
<td>Tip of papilla to interdental contact point</td>
<td></td>
</tr>
</tbody>
</table>
Pre-Operative Practice Visual Analogue Scale (VAS) Assessment

Black Box Series

1) How black/dark is this square?

Not at all ____________________________ Extremely

2) How black/dark is this square?

Not at all ____________________________ Extremely

3) How black/dark is this square?

Not at all ____________________________ Extremely

4) How black/dark is this square?

Not at all ____________________________ Extremely
Clinical Series

1. How would you rate this papilla fill?

2. How would you rate this papilla fill?
3. How would you rate this papilla fill?

![Image of papilla fill]

Not Satisfied  |  Very Satisfied

4. How would you rate this root coverage?

![Image of root coverage]

Not Satisfied  |  Very Satisfied
5. How would you rate this root coverage?

6. Are you happy with the overall aesthetics?
7. Are you happy with the overall aesthetics?

Before

After

Not Satisfied

Very Satisfied

8. Would you consider this treatment a success?

Before

After

Not Successful

Very Successful
9. Would you consider this treatment a success?

Clinical photos from:

1. How would you rate your papilla fill and/or root coverage?

Signature of (co-) investigator
By signing below, I declare that I have reviewed for accuracy the Case Report Form for this subject and this visit. The information contained on the pages for this visit and the entries made in the logs accurately reflects the dental records.

<table>
<thead>
<tr>
<th>Date</th>
<th>Name (CAPITALS):</th>
<th>Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
One-Week Post-Treatment Visit

**Date of Visit:** | | | | | | | |  
Day / Month / Year

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical attachment loss (CAL)</td>
<td>____ mm</td>
</tr>
<tr>
<td>Recession from cemento-enamel junction (CEJ) to free gingival margin (FGM)</td>
<td>____ mm</td>
</tr>
<tr>
<td>Tip of papilla to interdental contact point</td>
<td>____ mm</td>
</tr>
<tr>
<td>Calculated percentage of new root coverage</td>
<td>____ %</td>
</tr>
</tbody>
</table>

**Visual Analog Scale (patients only):**

**Section 1**

1. How would you rate your overall surgical experience?

[ ]

Not Satisfied  
Very Satisfied

2. How would you rate your surgical experience based on:

**Pain**

[ ]

Painless  
Unbearable

**Tolerance of Procedure**

[ ]

Comfortable  
Intolerable
3. How would you rate your surgical experience in comparison to other periodontal surgeries you have had based on:

**Pain**

Least                          Most

**Tolerance of Procedure**

Worst                          Best

**Post-operative recovery**

Worst                          Best
Section 2

1. How would you rate this papilla fill and/or root coverage?

| Not Satisfied | Very Satisfied |

2. Are you happy with the overall aesthetics?

| Not Satisfied | Very Satisfied |

3. Would you consider this treatment a success?

| Not Successful | Very Successful |

Signature of (co-) investigator

By signing below, I declare that I have reviewed for accuracy the Case Report Form for this subject and this visit. The information contained on the pages for this visit and the entries made in the logs accurately reflects the dental records.

<table>
<thead>
<tr>
<th>Name (CAPITALS):</th>
<th>Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

____/___/
(Day / Month / Year)
Six-Week Post-Treatment Visit

Date of Visit: ______/_____/_____

Clinical Measurements

<table>
<thead>
<tr>
<th>Clinical Measurements</th>
<th>__________mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical attachment loss (CAL)</td>
<td></td>
</tr>
<tr>
<td>Recession from cemento-enamel junction (CEJ) to FGM</td>
<td></td>
</tr>
<tr>
<td>Tip of papilla to interdental contact point</td>
<td></td>
</tr>
<tr>
<td>Calculated percentage of new root coverage</td>
<td>__________%</td>
</tr>
</tbody>
</table>

1. How would you rate your papilla fill and/or root coverage?

Not Satisfied                                      Very Satisfied

2. Are you happy with the overall aesthetics?

Not Satisfied                                      Very Satisfied

3. Would you consider this treatment a success?

Not Successful                                      Very Successful

Signature of (co-) investigator

By signing below, I declare that I have reviewed for accuracy the Case Report Form for this subject and this visit. The information contained on the pages for this visit and the entries made in the logs accurately reflects the dental records.

<table>
<thead>
<tr>
<th>Date</th>
<th>Name (CAPITALS):</th>
<th>Signature:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong><strong><strong>/</strong></strong><em>/</em></strong>___</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Six-Month Post-Treatment Visit

Date of Visit: [Day / Month / Year]

Clinical attachment loss (CAL) mm
Recession from CEJ to FGM mm
Tip of papilla to interdental contact point mm
Calculated percentage of new root coverage %

1. How would you rate your papilla fill and/or root coverage post-treatment?

<table>
<thead>
<tr>
<th>Not Satisfied</th>
<th>Very Satisfied</th>
</tr>
</thead>
</table>

2. Are you happy with the overall aesthetics?

<table>
<thead>
<tr>
<th>Not Satisfied</th>
<th>Very Satisfied</th>
</tr>
</thead>
</table>

3. Would you consider this treatment a success?

<table>
<thead>
<tr>
<th>Not Successful</th>
<th>Very Successful</th>
</tr>
</thead>
</table>

Signature of (co-) investigator

By signing below, I declare that I have reviewed for accuracy the Case Report Form for this subject and this visit. The information contained on the pages for this visit and the entries made in the logs accurately reflects the dental records.

Name (CAPITALS): Signature:

___ / ____ / ____
(Day / Month / Year)
Contributions to the Thesis Manuscript

Stephen Spano is responsible for all contents of this thesis. All aspects of the clinical research pertaining to this thesis, including case report form development, patient consults, surgeries, follow-ups, measurements, VAS assessments and statistical analysis were performed solely by Stephen Spano.
References


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70. Mansouri SS, Ghasemi M, Salmani Z. Clinical application of hyaluronic acid gel for reconstruction of interdental papilla at the esthetic zone. *Journal of Islamic Dental …. 
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