### Implants Inserted Into Homografts Bearing Fixed Restorations

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> Purpose: In the last decade several studies have evaluated the clinical outcome of implants inserted into autografts and rehabilitated with fixed restorations in either oneor two-step surgical protocols. However, no study has investigated implants placed into homografts; thus, a case series analysis was performed to verify the clinical outcome of implants inserted into fresh frozen bone (FFB) and bearing fixed prosthetic restorations. Materials and Methods: Fifty-eight patients underwent iliac crest homograft transplants and 238 implants were inserted. Seventy-one double-etched, 19 sandblasted and acid-etched-1 (SLA<sub>1</sub>), 10 grit-blasted and acid-etched, 73 anodic oxidized, 39 CaPo<sub>4</sub> ceramic-blasted, 19 SLA<sub>2</sub>, and seven additional implants of various types were used. Implant diameter and length ranged from 3 to 5 mm and from 7 to 16 mm, respectively. Implants were inserted to replace 15 incisors, 14 canines, 102 premolars, and 107 molars. A total of 111 restorations were performed. Results: No implants were lost. Cox regression analysis showed that implant type and type of edentulism directly correlated with a lower bone resorption and thus had a better clinical outcome and success rate. Conclusion: Implants bearing fixed restorations and inserted into FFB have higher survival and succes rates compared to those placed in nongrafted and grafted jaws reported in previous studies. Int J Prosthodont 2009;22:148-154

A fixed prosthesis (FP) is a device used to replace missing teeth that is cemented or screwed onto natural and/or artificial abutments. FPs give higher psychological, functional, and esthetic results when compared to removable dentures.<sup>1</sup>

FPs can be built on implants to restore teeth without the need for natural pillars. In addition, implants have positive effects on alveolar crest bone maintenance.<sup>2</sup> The success of the treatment depends on careful presurgical planning and prosthesis design. Clinical trials have demonstrated high survival and success rates for implants supporting FPs.<sup>3,4</sup> The insertion of endosseous implants is often difficult due to a lack of supporting bone. Ideally, skeletal defects should be corrected with autologous bone by replacement or augmentation, although autografts are considered the gold standard procedure for bone grafting. Moreover, autologous bone grafts have the drawback of requiring secondary surgery for autograft retrieval, with increased operation time, anesthesia, and donor site morbidity.<sup>5</sup> On the other hand, biomaterials are also good but expensive, and may extrude at a later date.<sup>6</sup> Therefore, the use of homograft bone provides a reasonable alternative to meet the demand for graft material.<sup>5,6</sup>

Bone homograft transplantation has been performed in humans for more than 100 years and has been increasingly used by orthopedic surgeons.<sup>7</sup> Many forms of banked bone homograft are available to the surgeon: fresh frozen bone (FFB), freeze-dried bone (FDB), and demineralized fresh dried bone (DFDB).<sup>8</sup> Regarding the use of FFB in oral and maxillofacial surgery, only two reports are available in the literature. Perrot et al<sup>9</sup> used FFB in combination with autologous bone from the iliac crest to restore atrophic jaws (eight patients) and alone in one case of ameloblastoma and one case of

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myxoma of the mandible (two patients), yielding a survival rate of 95.8% (one implant out of 29 lost). Rochanawutanon et al<sup>10</sup> later demonstrated that even after resecting large portions of the mandible, FFB can be used. They reported four cases with a follow up of over 12 years.

Since FFB has an ever-increasing number of clinical applications and no report specifically focuses on implants inserted into homografts bearing fixed prosthetic restorations, the authors decided to perform this retrospective study.

### **Materials and Methods**

### Patients

In the period between December 2003 and December 2006, 81 patients (52 females and 29 males, median age:  $52 \pm 9$  years) were operated on at the Civil Hospital in Castelfranco Veneto, Italy. Among them, 58 patients (33 females and 25 males, median age: 53 years; 11 with complete and 47 with partial edentulism) received maxillary FFB homografts and implants were inserted. A total of 111 fixed implant prosthesis were delivered. Informed written consent approved by the local ethics committee was obtained from all patients to use their data for research purposes. The mean postloading follow-up for the implants was 26 months (range: 7 to 43 months).

FFB grafts were inserted into patients' jaws under general anesthesia. In most cases, the mean postgrafting period was 6 months before implant surgery and the final prosthetic restoration was delivered after an additional 6 months.

Subjects were screened according to the following inclusion criteria: controlled oral hygiene, the absence of any lesions in the oral cavity, and sufficient residual bone volume (residual bone plus the FFB graft) to receive implants of 3 mm in diameter and 7 mm in length. In addition, patients had to agree to participate in a postoperative checkup program.

Exclusion criteria were as follows: a high degree of bruxism; smoking more than 20 cigarettes per day or excessive consumption of alcohol; localized radiation therapy of the oral cavity; anti-tumor chemotherapy; liver, blood, or kidney diseases; immunosuppressed patients; patients taking corticosteroids or bisphosphonates; pregnant women; inflammatory or autoimmune diseases of the oral cavity; and poor oral hygiene.

### Graft Material

The FFB obtained from the Veneto Tissue Bank in Treviso, Italy was a mineralized, nonirradiated, disinfected, frozen homologous bone. The bone harvesting was obtained from the anterior and posterior iliac crest in the first 12 hours after donor death. The bone was then disinfected for at least 72 hours at  $-4^{\circ}$ C in a polychemotherapeutic solution of vancomycine, polymyxine, glazidine, and lincomycine. Following that, the sample was irrigated with a sterile saline solution and then subdivided into cortico-medullary blocks, packed in double sterile casing and frozen at  $-80^{\circ}$ C.

The requirements for homologous bone donors are more stringent with respect to those for organ donors. The presence of risk factors such as contagious disease, neoplasm, rheumatic and/or degenerative disease, and sepsis almost entirely disgualified the donor. In order to detect infectious agents, the following tests were performed on donor blood samples taken within 8 hours of death: anti-HIV-I/II Ab, anti-HCV Ab, HbsAg, anti-HBc Ab, anti-HBs Ab, anti-HTLV-I/II Ab, anti-Ag Treponemal Ab, anti-CMV IgG Ab, anti-CMV IgM Ab, anti-Toxoplasma IgG Ab, and anti-Toxoplasma IgM Ab. A culture was also performed to detect aerobic and anaerobic bacteria, mycobacteria, and mycotical agents. As a further safety precaution, a serological follow-up was conducted using polymerase chain reaction techniques to detect any viral RNA or DNA of HIV, HCV, and HBV. This method reduces the diagnostic window period to 7 days for these autoimmune diseases.

lliac bone homografts were composed of both cancellous and cortical bone. They were usually inserted as en block grafts and fixed with screws.

### Data Collection

Before surgery, radiographic examinations were completed with the use of orthopantomographs and computed tomography (CT) scans. The same panoramic unit was used for all data collection, and bone resorption was normalized with respect to implant length.

In each patient, peri-implant crestal bone levels were evaluated by the calibrated examination of orthopantomographs. Measurements were recorded before surgery, after surgery, and at the end of the follow-up period. The measurements were carried out mesially and distally to each implant, calculating the distance between the edge of the implant and the most coronal point of contact between the bone and implant. The bone level recorded just after the surgical insertion of the implant served as the reference point for these measurements. Each measurement was rounded off to the nearest 0.1 mm. A peak Scale Loupe with a magnifying factor of seven times and a scale graduated by 0.1 mm was used.

Peri-implant probing was not performed since controversy still exists regarding the correlation between probing depth and implant success rates.<sup>11,12</sup> Implant success rate was evaluated according to the absence of the following criteria: persistant pain or dysesthesia, peri-implant infection with suppuration, mobility, and persistant peri-implant bone resorption greater than 1.5 mm during the first year of loading and 0.2 mm per year thereafter.<sup>13</sup>

### Implants

A total of 238 implants were inserted into 58 patients; 163 (68.5%) and 75 (31.5%) in partially and completely edentulous patients, respectively. Twenty-four (10.1%) were placed in the mandible and 214 (89.9%) in the maxilla. There were 71 double-etched (3i, Biomet), 19 sandblasted and acid-etched-1 (SLA<sub>1</sub> - Astra, Astratech), 10 grit-blasted and acid-etched (Frialit, Dentsply Friadent ), 73 anodic oxidized (Nobel Biocare, TiUnite, Nobel Biocare), 39 CaPo<sub>4</sub> ceramic-blasted (RBM, Lifecore Biomedical), 19 SLA<sub>2</sub> (Sweden & Martina, Sweden & Martina Spa) and seven other various types including two ITI (Straumann), two Pit-Easy (Oraltronics), two Endopore (Innova) and one Biotech (Povolaro di Dueville). Implant diameter ranged from 3 to 5 mm and length from 7 to 16 mm. Implants were inserted to replace 15 incisors, 14 canines, 102 premolars, and 107 molars.

### Surgical and Prosthetic Technique

All patients underwent the same surgical protocol. Five hundred mg amoxicillin was administered twice daily for 5 days starting 1 hour before surgery to prevent bacterial infection. Local anesthesia was induced using articaine/epinephrine and postsurgical analgesic treatment included 100 mg nimesulid twice daily for 3 days. Oral hygiene instructions were provided and included the use of chlorhexidine rinses twice daily for 1 week.

After making a crestal incision, a mucoperiosteal flap was elevated. Implants were inserted according to the recommended procedures and the implant platform was positioned at the alveolar crest level. Silk sutures (triple 0) were used and removed 14 days after surgery. Twenty-four weeks after implant insertion, the provisional prosthesis was provided; the final restoration was delivered within an additional 8 weeks. The number of prosthetic units (ie, implant/crown ratio) was about 0.8. All patients were included in a strict hygiene recall (Figs 1 to 7).

A total of 111 fixed restorations were delivered: 70 implants supported single-tooth crowns; 4 and 26 fixtures carried fixed partial dentures on implants with and without cantilevers, respectively; one fixed partial denture supported by both implants and teeth had cantilevers, whereas the remaining 10 built on mixed pillars had no cantilevers. Table 1 reports the number of restorations per prosthetic type crossed with antagonists and median number of prosthetic units (NPU).

### Statistical Analysis

Since no implants were lost, reduced or no crestal bone resorption was considered an indicator of success to evaluate the effects of several host-, implant-, and occlusion-related factors.

The difference between the implant abutment junction and the bone crestal level was defined as the Implant Abutment Junction (IAJ) and calculated at the time of operation and throughout follow-up.  $\Delta$ IAJ is the difference between the IAJ at the last checkup and the IAJ recorded just after the operation.  $\Delta$ IAJ medians were stratified according to variables of interest.

Disease-specific survival curves were calculated according to the product-limit method (Kaplan-Meier algorithm).<sup>14</sup> Baseline was defined as the date of implant insertion. Implants that were still in place at the time of the last follow-up were included in the total number at risk of suffering loss only up until this time point. Therefore, the survival rate only changed when implant loss occurred. The calculated survival rate was the maximum estimate of the true survival curve. Log rank testing was used to compare survival curves, generated by stratifications for variables of interest.

Cox regression analysis was then applied to determine the single contribution of covariates on the survival rate. Cox regression analysis compares survival data while taking into account the statistical value of independent variables, such as age and sex, on whether or not an event (ie, implant loss) is likely to occur. If the associated probability was less then 5% (*P* < .05), the difference was considered statistically significant. In the process of completing the regression analysis, the odds ratio and 95% confidence bounds were calculated. Confidence bounds did not have to include the value 1.<sup>15</sup> Stepwise Cox analysis was used to detect the variables most associated with implant survival and/or success.

### Results

Tables 2 through 7 report the median  $\Delta$ IAJ according to the studied variables. No implants were lost in the postoperative period. Cox Regression analysis (Table 8) demonstrates that implant type and type of edentulism correlated with a lower  $\Delta$ IAJ and thus, a better clinical outcome.



**Fig 1** Endo-oral photograph showing the absence of three maxillary right elements (two premolar and one molar).



Fig 2 Presurgical orthopantomograph.



Fig 3 The homograft.





**Fig 4** *(left)* Sinus lift using an en block homograft and immediate insertion of implants.

**Fig 5** (*right*) Control image taken 4 months post–implant insertion.



**Fig 7** (*right*) Final prosthetic rehabilitation.





Table 1 Type of Restoration Crossed with Antagonist Elements (Median NPU)

		Implants bearing FPD		Implants and teeth bearing FPDs		
Antagonist	Single-tooth crowns	With cantilevers	Without cantilevers	With cantilevers	Without cantilevers	
Natural teeth	44 (1)	1 (0.8)	5 (0.7)	0	3 (0.7)	
Natural teeth and prostheses	16 (1)	3 (0.8)	8 (0.8)	0	6 (0.7)	
Prostheses only	10 (1)	0	13 (0.6)	1 (0.7)	1 (0.7)	

FPDs = fixed partial dentures.

 $\label{eq:constraint} \textbf{Table 2} \quad \text{Distribution of Series Regarding Graft Site and $\Delta$IAJ}$ 

Graft site	n	ΔIAJ	
Maxilla	214	$1.5 \pm 1.5$	
Mandible	24	$1.8 \pm 1.4$	

# Table 3 Distribution of Series Regarding Implant Site and $\Delta IAJ$

Implant site	n	ΔΙΑΙ	
Incisor	15	1.0 ± 2.1	
Canine	14	$1.5 \pm 1.9$	
Premolar	102	$1.5 \pm 1.4$	
Molar	107	$1.5 \pm 1.5$	

Table 4 Distribution of Series Regarding Implant Length and  $\Delta IAJ$ 

Implant length	n	ΔΙΑΙ	
< 13 mm	34	$1.5 \pm 1.1$	
= 13 mm	152	$1.7 \pm 1.5$	
>13 mm	52	$1.5 \pm 1.6$	

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Implant diameter	n	ΔΙΑΙ	
< 3.75 mm	69	$1.5 \pm 1.6$	
= 3.75 mm	75	$2.0 \pm 1.0$	
> 3.75 mm	94	$1.5 \pm 1.7$	

## **Table 6** Distribution of Series Regarding Implant Type and $\Delta IAJ$

Implant type	n	ΔΙΑΙ
Double-etched	71	1.5 ± 1.0
SLA <sub>1</sub>	19	$3.0 \pm 2.0$
Grit-blasted and acid-etched	10	$6.0 \pm 2.4$
Anodic oxidized	73	$1.5 \pm 1.3$
CaPo, ceramic-blasted	39	$1.5 \pm 0.7$
SLA <sub>2</sub>	19	$1.0 \pm 0.3$
Other	7	2.0 ± 1.0

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Edentulism type	n	ΔΙΑJ	
Partial	163	$1.5 \pm 1.5$	
Total	75	$1.5 \pm 1.6$	

Table 8Cox Regression Analysis Reporting Variables Statistically Associated with  $\Delta IAJ$ 

			Significance	95% confidence interval	
Variable	В	SE	( <i>P</i> <.05)	Lower	Upper
Age	0.0060	0.0147	.6812	.9775	1.0355
Gender	-0.4046	0.2747	.1407	.3895	1.1431
Graft site	0.7342	0.4364	.0925	.8859	4.9011
Implant site	0.1978	0.1570	.2077	.8959	1.6579
Implant length	0.0114	0.2329	.9610	.6408	1.5965
Implant diameter	0.0208	0.1570	.8948	.7506	1.3888
Implant type	-0.2680	0.0707	.0010*	.6659	.8786
Type of edentulism	-1.4274	0.2928	.0010*	.1352	.4259

\*Statistically significant variables.

### Discussion

The concept of osseointegration, the direct anchorage of endosseus implants made of commercially pure or titanium alloy to bone, has caused a breakthrough in oral rehabilitation.<sup>16</sup> In many cases, the insertion of endosseous implants is difficult because of a lack of supporting bone. In the case of severe atrophy of the jaws, a large volume of autogenous bone can be harvested from the iliac crest and inserted into both jaws. In recent years, several reports have focused on implants inserted into iliac crest bone autografts to identify guidelines for survival and success rates.<sup>17-23</sup> Variables influencing the final result are usually grouped as surgery-, host-, implant-, or occlusionrelated factors.<sup>24</sup> To the authors' best knowledge, no reports are available on bone resorption in implants bearing fixed prostheses inserted into homografts.

Previous reports on implants inserted into autologous iliac crest bone grafts showed a survival rate ranging from 85% to 95%. In this case, implants were inserted with a two-stage surgical technique and the vast majority of failures occurred within the first year of loading.<sup>17-23</sup> In the present study, a survival rate of 100% was obtained after an average period of 20 months post-loading. Based on this outcome, FFB seems to be a reliable material for the insertion of implants.

Among the implant-related factors, length (Table 4), diameter (Table 5), and type of prosthesis (Table 6) are considered to be the most relevant. In the present study, length and diameter have no statistically significant impact on the success rate, whereas the use of  $SLA_1$  and anodic oxidized implants gave a limited clinical advantage. Additional studies are needed to verify whether surface type is a critical point.

Bone quality, a host-related factor, is believed to be one of the strongest predictors of outcome and several reports are available on implants inserted into native bone.<sup>25,26</sup> Our data showed that FFB is an effective material to restore alveolar ridge volume since no implants were lost and marginal bone resorption surrounding implants was small.<sup>18,19,21</sup> Widmark et al<sup>18</sup> reported a mean marginal peri-implant bone loss of 0.6 mm during the period from prosthesis connection to the 1-year follow-up, and from the 1-year to the 3-year follow-up, average peri-implant bone loss was 0.3 mm. Sjöström et al<sup>19</sup> presented a change in the marginal bone level of  $0.3 \pm 0.3$  mm between the baseline (fixed partial denture delivery) and the 3-year follow-up. Barone and Covani<sup>21</sup> described a mean bone loss around implants of 0.3  $\pm$  0.4 mm at implant placement and 0.1  $\pm$  0.3 mm 6 months after placement.

Among the occlusal-related factors, restoration type can potentially influence the clinical outcome. Since in the present study there were several types of prosthetic restorations, each group had a limited size, no implant was lost, and there was a globally high success rate. No statistical difference was seen among the different types of prostheses.

Type of edentulism was statistically significant in terms of the success rate, with better results for patients who had total edentulism (Table 7). This is not surprising since partially edentulous patients, especially those with a history of chronic periodontitis, may exhibit significantly greater long-term probing pocket depth, peri-implant marginal bone loss, and incidence of peri-implantitis when compared to periodontally healthy or completely edentulous subjects.<sup>27</sup>

### Conclusions

FFB is a reliable grafting material for oral rehabilitation with fixed prosthetic implant restoration. Implants inserted into FFB and bearing fixed restorations have high survival and success rates similar to those reported in previous studies on grafted bone. Implants inserted into FFB can be considered reliable, although a worse clinical outcome is to be expected in partially edentulous patients and when certain implant types are used.

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### References

- Sadowsky SJ. An overview of treatment considerations for esthetic restorations: A review of the literature. J Prosthet Dent 2006;96:433-442.
- 2. Tinsley D, Watson CJ, Preston AJ. Implant complications and failures: The fixed prosthesis. Dent Update 2002;29:456–460.
- Degidi M, Piattelli A, Gehrke P, Felice P, Carinci F. Five-year outcome of 111 immediate nonfunctional single restorations. J Oral Implantol 2006;32:277–285.
- Degidi M, Piattelli A, Felice P, Carinci F. Immediate functional loading of edentulous maxilla: A 5-year retrospective study of 388 titanium implants. J Periodontol 2005;76:1016–1024.
- Vargel I, Tunçbilek G, Mavili E, et al. Solvent-dehydrated calvarial allografts in craniofacial surgery. Plast Reconstr Surg 2004;114:298–306.
- Gajiwala K, Lobo Gajiwala A. Use of banked tissue in plastic surgery. Cell Tissue Bank 2003;4:141–146.
- Tomford WW, Mankin HJ. Bone banking. Update on methods and materials. Orthop Clin North Am 1999;30:565–570.
- Hardin CK. Banked bone. Otolaryngol Clin North Am 1994;27:911-925.
- Perrot DH, Smith Ra, Kaban LB. The use of fresh frozen allogeneic bone for maxillary and mandibular reconstruction. Int J Oral Maxillofac Surg 1992;21:260–265.
- Rochanawutanon S, Suddhasthira T, Pairuchvej V, Vajaradul Y. Long term follow-up of reconstruction of allogeneic mandibular bone crib packed with autogenous particulate cancellous bone marrow. Cell Tissue Bank 2002;3:183–197.
- Quirynen M, van Steenberghe D, Jacobs R, Schotte A, Darius P. The reliability of pocket probing around screw-type implants. Clin Oral Implants Res 1991;2:186–192.
- Quirynen M, Naert I, van Steenberghe D, Teerlinck J, Dekeyser C, Theuniers G. Periodontal aspects of osseointegrated fixtures supporting an overdenture. A 4-year retrospective study. J Clin Periodontol 1991;18:719–728.
- Albrektsson T, Zarb GA. Determinants of correct clinical reporting. Int J Prostodont 1998;11:517–521.
- 14. Dawson-Saunders B, Trapp RG. Basic & Clinical Biostatistic. Norwalk: Appleton & Lange, 1994.
- 15. Cox DR, Oakes D. Analysis of Survival Data. New York: Chapman & Hall, 1984.
- Adell R, Lekholm U, Rockler B, Brånemark PI. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. Int J Oral Surg 1981;10:387–416.
- Schliephake H, Neukam FW, Wichmann M. Survival analysis of endosseous implants in bone grafts used for the treatment of severe alveolar ridge atrophy. J Oral Maxillofac Surg 1997;55:1227–1233.
- Widmark G, Andersson B, Carlsson GE, Lindvall AM, Ivanoff CJ. Rehabilitation of patients with severely resorbed maxillae by means of implants with or without bone grafts: A 3- to 5-year follow-up clinical report. Int J Oral Maxillofac Implants 2001;16:73–79.
- Sjöström M, Sennerby L, Nilson H, Lundgren S. Reconstruction of the atrophic edentulous maxilla with free iliac crest grafts and implants: A 3-year report of a prospective clinical study. Clin Implant Dent Relat Res 2007;9:46–59.
- Chiapasco M, Brusati R, Ronchi P. Le Fort I osteotomy with interpositional bone grafts and delayed oral implants for the rehabilitation of extremely atrophied maxillae: A 1-9-year clinical follow-up study on humans. Clin Oral Implants Res 2007;18:74–85.
- Barone A, Covani U. Maxillary alveolar ridge reconstruction with nonvascularized autogenous block bone: Clinical results. J Oral Maxillofac Surg 2007;65:2039–2046.

- Bell RB, Blakey GH, White RP, Hillebrand DG, Molina A. Staged reconstruction of the severely atrophic mandible with autogenous bone graft and endosteal implants. J Oral Maxillofac Surg 2002;60:1135–1141.
- Marchetti C, Trasarti S, Corinaldesi G, Felice P. Interpositional bone grafts in the posterior mandibular region: A report on six patients. Int J Periodontics Restorative Dent 2007;27:547–555.
- Gapski R, Wang HL, Mascarenhas P, Lang NP. Critical review of immediate implant loading. Clin Oral Implants Res 2003;14:515–527.
- Colomina LE. Immediate loading of implant-fixed mandibular prostheses: A prospective 18-month follow-up clinical study– Preliminary report. Implant Dent 2001;10:23–29.
- Balshi TJ, Wolfinger GJ. Immediate loading of Brånemark implants in edentulous mandibles: A preliminary report. Implant Dent 1997;6:83–88.
- Karoussis IK, Kotsovilis S, Fourmousis I. A comprehensive and critical review of dental implant prognosis in periodontally compromised partially edentulous patients. Clin Oral Implants Res 2007;18:669–679.

#### Literature Abstract

Safety and effectiveness of topical dry mouth products containing olive oil, betaine, and xylitol in reducing xerostomia for polypharmacy-induced dry mouth

This is an investigation to evaluate the safety and efficacy of a group of topical dry mouth products (Xerostom). These products containing olive oil, betaine, and xylitol were developed to reduce xerostomia. In the form of toothpaste, mouth rinse, mouth spray, and gel, these products were tested in a population of adults experiencing polypharmacy-induced salivary hypofunction and xerostomia. Forty adults were selected into a single-blinded, open-label, cross-over clinical study where 39 subjects completed all the visits. These subjects were randomly assigned at baseline either (1) to using the novel topical dry mouth products daily for a week or (2) to maintain their normal dry mouth care routine. One week later, the subjects were switched to the other dry mouth regimen. Measurements before and after the study included collection of unstimulated whole saliva, administering an 8-item 100 mm dry mouth VAS questionnaire, and a xerostomia-related quality of life questionnaire. Comparisons of baseline measurements were conducted using Student t tests. Analyses were carried out using SAS version 9+. A P-value of .05 was accepted for statistical significance. Results indicated the use of Xerostom products for 1 week led to a significantly greater increase in unstimulated whole salivary flow rates (0.05 ± 0.05 mLmin-1 to 0.140 ± 0.26 mLmin-1) than subjects' normal dry mouth routine for a week (0.047 ± 0.05 mLmin-1 to 0.05 mLmin-1) (P = .033). Dry mouth symptoms assessed using the 8-item VAS questionnaire indicated that the use of Xerostom products produced greater overall improvement compared with subjects' normal dry mouth routines for the same period (P = .011). The effect of xerostomia on a subject's quality of life was assessed with a 15-item survey and the overall results also demonstrated a greater improvement in the group that used topical dry mouth products. The results demonstrated that the use of novel topical dry mouth products significantly increased unstimulated whole salivary flow rates, reduced complaints of xerostomia, and improved xerostomia-associated quality of life. There were no clinically significant adverse events noted. It is therefore concluded that the use of topical dry mouth products containing olive oil, betaine, and xylitol is safe and effective in relieving symptoms of dry mouth in a population with polypharmacy-induced xerostomia.

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