Patient Discomfort Following Single-Tooth Implant Placement: A Randomized Controlled Trial of Immediate vs. Conventional Tooth Restoration

Rubens Spin-Neto[1], Ana Emília Farias Pontes[2], Ann Wenzel[3], Celso Eduardo Sakakura[2]

[1]PhD student, Oral Radiology, Department of Dentistry, Aarhus University, Aarhus, Denmark. [2]Associate Professor, Educational Foundation of Barretos (UNIFEB), Barretos, São Paulo, Brazil. [3]Professor and Head, Oral Radiology, Department of Dentistry, Aarhus University, Aarhus, and Copenhagen University, Copenhagen, Denmark.

Abstract

Aims: Evaluate postoperative discomfort (pain, bleeding and swelling) in single-tooth implant patients submitted to immediate or conventional tooth restoration together with assessment of treatment time.

Methods: Twenty-four patients who received single-tooth maxillary dental implants were randomly assigned to an IR (Immediate Restoration) or CR (Conventional Restoration) group. In IR, an implant was inserted and a provisional tooth crown was delivered within the same session, while in CR it was delivered three months after implantation. Pain (first three days), bleeding (first day) and swelling (first seven days) were assessed using a questionnaire with Visual Analogue Scales (VAS).

Results: Treatment time was longer for IR than for CR (57 ± 14 and 33 ± 8 min, respectively; $p<0.0001$). Mean VAS scores for pain, bleeding, and swelling were low for both groups at the first postoperative day. VAS scores for pain and swelling decreased continuously over the time period in both groups.

Conclusions: The longer treatment time in IR didn't increase patients' perception of pain, bleeding and swelling, compared to CR. The impact of immediate tooth restoration on patients' esthetic outcome should be further considered.

Key words: Dental implants, Discomfort, Immediate loading, RCT

Introduction

Single-tooth implants followed by immediate prosthetic loading have shown success rates similar to those submitted to the conventional loading protocol [1,2]. In general, there is a high level of comparative evidence supporting the use of both immediate and conventional loading of single implant crowns in terms of implant survival and marginal bone level stability [2]. The immediate restoration technique has advantages such as an immediate-satisfying esthetic outcome, maintenance of the gingival contour [3], lack of a second-phase surgery, and the presence of a fixed, implant-supported, provisory crown. On the other hand, the treatment session is longer since the prosthetic procedures are mostly performed in the same session as implant installation [1,2]. This might result in more severe postoperative discomfort, since swelling and pain has been shown to be proportional to the operation time and the extension of the dental procedure [4].

Little documentation exists on the patients' view of the different methods related to implant placement and subsequent tooth restoration. Previous studies have evaluated patient's postoperative discomfort after apicectomy and retrograde root filling [5], orthogonal endodontic treatment [6], among others. However, to the best of our knowledge, reports with regards to postoperative discomfort after implant installation surgery are rare in the current literature, specifically regarding the use of single-tooth implants submitted to immediate loading [7].

Aims

This study evaluates postoperative discomfort in relation to pain, bleeding, and swelling, together with treatment time, in patients treated with a single-tooth implant and thereafter randomized to two groups: immediate mounting of the tooth restoration or conventional restoration after three months.

Methods

Patient selection

This study was a blinded, parallel-group study with balanced randomization, approved by the Educational Foundation of Barretos Ethics Committee (protocol #098/2007). Each subject signed a written consent form, and the study was conducted in full accordance with the World Medical Association Declaration of Helsinki.

Eligible patients were those who attended the clinic with the wish for a single-tooth dental implant in the maxillary incisor, canine or premolar region. Primary exclusion criteria were systemic diseases that may interfere with bone metabolism, parafunctional habits, alcohol abuse and use of tobacco. Patients presenting visible plaque [8] or bleeding-on-probing [9] in more than 20% of tooth surfaces (considering all teeth) at baseline, or planned implant sites with insufficient crestal bone width (evaluated by subjective clinical assessment) for implant installation were also excluded (i.e. patients in need of bone or soft tissue regenerative procedures were not included in the study sample). Twenty-four consecutive patients, who sought treatment at the Implantology Clinic in Educational Foundation of Barretos, fulfilled the eligibility criteria and accepted to participate. The average time from tooth extraction to implant installation was six months, ranging from three to twelve. Based on this sample size, the power of this study was 0.90, considering patients' VAS scores for pain reported by Urban and Wenzel in 2010 [7].

Implant installation

All implants had a conic shape (Alvim II plus, NEODENT, Curitiba, Brazil) with internal hexagon connection. The platform diameter was 4.3 mm, and the diameter of the correspondent prosthetic abutment was 3.8 mm. Surface was aluminum-oxide-blasted and acid-etched. Implants were 10 mm, 13 mm, or 16 mm in length depending on region.

Corresponding author: Rubens Spin-Neto, PhD student, Oral Radiology, Department of Dentistry, Aarhus University, Aarhus, Denmark, Tel: +454-2434-836; e-mail: rsn@odont.au.dk

Before implant placement, extra- and intra-oral antisepsis was performed with 0.12% Chlorhexidine-digluconate solution. Local anesthesia was administered with Mepivacaine 2% HCl with Norepinephrine 1:100.000. A crestal incision was performed, maintaining adequate quantities of keratinized tissue on each side of the incision. Intrasulcular incisions were performed for adjacent teeth. Buccal and palatal mucoperiosteal flaps were obtained to directly access bone. Dental implants were placed according to manufacturer's recommendation using 1200 rpm for drilling and abundant irrigation with sterile saline solution. Insertion was performed with manual wrench, associated to a torque meter. Implants were inserted 2 mm apical to the cemento-enamel junction of adjacent teeth, maintaining at least 1 mm of the buccal bone plate covering the threads. It was part of the protocol that implants showing insertion torque lower than 40 N.cm or higher than 90 N.cm would be excluded from the sample, but this situation never occurred.

Patient randomization

Immediately after implant placement, the patient was randomly assigned to one of the two treatment groups in a closed randomization design tossing a coin (immediate tooth restoration, IR group, or conventional tooth restoration, CR group), by an investigator with no clinical involvement in the trial. When one of the groups was complete (12 subjects), all subsequent patients were assigned to the other group. Demographic data on the groups are presented in *Table 1*.

Patients assigned to the IR group had a provisional tooth crown, mounted on a UCLA abutment, delivered immediately after surgery. Patients in the CR group had a cover screw installed on top of the implant, which was left submerged. Three months later, an impression was taken, and a healing cap and tooth crown were delivered.

Postoperative care

Patients were given postoperative written instructions, suggesting the ingestion of cold and soft food on the first days following surgery, together with the use of cold compresses on the operated region. Patients were also asked to repose in the first 24 hours after the operation. Patients were prescribed antibiotics (500 mg Amoxicillin, every 8 hours, for 7 days), and anti-inflammatory treatment (100 mg Nimesulide, every 12 hours, for 4 days). In addition, oral rinsing with 0.12% Chlorhexidine-digluconate was also prescribed (every 12 hours, for 7 days). All patients were also instructed in oral hygiene.

Treatment time assessment

The assessment of treatment time was performed using a digital chronometer, which was started together with the local anesthesia administration. For CR group the chronometer was stopped when the healing abutment was placed in position. For IR group the end of the procedure was defined when the crown was mounted.

Patient satisfaction and discomfort assessment

Postoperative patient satisfaction with the information provided before and after the surgery, and discomfort (pain, swelling, bleeding, and need for additional medication or health care) were assessed by a questionnaire (*Box 1*) applied to all patients. Questions 1 to 10, and 15 to 18 were answered by marking a cross on a 100-mm Visual Analogue Scale (VAS). Questions 11 to 14 demanded a dichotomous answer (yes/no).

The form with the questions and their respective VAS was given to the patients, and they were asked to fill it in every evening, considering the worst score of the day for each question. For the VAS reflecting patient satisfaction, the end points of the scale were "not satisfied at all" and "totally satisfied". Patient satisfaction was assessed only on the day of the surgery. For the VAS reflecting discomfort, the end points of the scale were "no pain, swelling, or bleeding" at all and "immense pain, swelling, or bleeding". Pain was assessed two-to-three hours, and one, two and three days after surgery. Swelling was assessed each day after surgery for seven days. Bleeding was assessed only on the first postoperative day.

Data treatment and statistical analyses

The unit of analysis was the patient (one implant per patient). Statistical analyses were performed using specific software (MedCalc Software version 12.2.1.0, Mariakerke, Belgium), and the level of significant was set at 5%.

The patients' VAS scores were measured using a ruler and rounded off to the nearest mm. Normality distribution of continuous data (VAS and treatment time) was analyzed using Shapiro-Wilk test. Except for treatment time (*t*-test), data showed non-normality distributions, so comparison between groups was performed using non-parametric Wilcoxon's test. For multiple comparisons, Friedman test was used. Dichotomous data were analyzed by Fisher's exact test. Spearman's correlation analysis was used to analyze the association between treatment time and VAS data.

Results

Treatment time was almost twice as long for the IR group (57 ± 14 minutes) compared to the CR group (33 ± 8 minutes) ($p<0.0001$).

Patients in both groups expressed to be highly satisfied with the information provided both before and after the surgery. There were no significant differences between the groups for any of the parameters from the questionnaire (*Tables 2* and *3*). Therefore, for pain, swelling, and bleeding, groups were pooled to assess discomfort over time.

Table 1. *Demographic characteristics of the study population.*

Parameter	Total	Inter-group analysis		
		IR	CR	p-value
Age (years, mean ± SD)	39.5 ± 9.7	40.8 ± 9.6	38.1 ± 9.8	ns*
Implant region	5 Incisors 3 Canines 15 Premolars 1 Molar	3 Incisors 1 Canine 8 Premolars 0 Molars	2 Incisors 2 Canines 7 Premolars 1 Molar	ns**

* Wilcoxon's test; ** test of contingency; ns=non-significant.

On the day of surgery:
(Q1) Were you satisfied with information provided orally before the surgery?
(Q2) Were you satisfied with information provided orally after the surgery?
(Q3) How was the pain after termination of the analgesic effect (2 to 3 hours after surgery)?
On the first day after surgery:
(Q4) How was the pain on the first day after surgery?
(Q5) How was the swelling on the first day after surgery?
(Q6) How was the bleeding on the first day after surgery?
On the second day after surgery:
(Q7) How was the pain on the second day after surgery?
(Q8) How was the swelling on the second day after surgery?
On the third day after surgery:
(Q9) How was the pain on the third day after surgery?
(Q10) How was the swelling on the third day after surgery?
On the first to fourth day after surgery:
(Q11) Did you take any medication in addition to the prescription?
(Q12) Were you unable to work? If yes, for how many days?
(Q13) Did you need to call a dentist or doctor due to surgical complications?
(Q14) Did you need any additional treatment due to surgical complications?
On the fourth to seventh day after surgery:
(Q15) How was swelling on the fourth day after surgery?
(Q16) How was swelling on the fifth day after surgery?
(Q17) How was swelling on the sixth day after surgery?
(Q18) How was swelling on the seventh day after surgery?

Box 1. *Questionnaire applied to the patients.*

Table 2. *VAS scores (mean; median; range), for the IR and CR groups and total.*

Parameter	Total	Inter-group analysis		
		IR	CR	p-value
Information provided before (Q1)	95; 96; 75 – 100	94; 95; 75 – 100	96; 97; 87 – 100	ns
Information provided after (Q2)	93; 96; 75 – 100	94; 96; 55 – 100	92; 96; 55 – 100	ns
Pain, 2-3 hours after (Q3)	25; 21; 0 – 95	26; 18; 0 – 95	24; 24; 3 – 54	ns
Pain, 1st day after (Q4)	16; 5; 0 – 95	18; 4; 0 – 95	15; 10; 3 – 63	ns
Pain, 2nd day after (Q7)	11; 4; 0 – 65	11; 4; 0 – 65	10; 4; 0 – 47	ns
Pain, 3rd day after (Q9)	6; 3; 0 – 46	8; 3; 0 – 46	5; 3; 0 – 25	ns
Swelling, 1st day after (Q5)	23; 7; 0 – 100	17; 4; 0 – 78	30; 29; 0 – 100	ns
Swelling, 2nd day after (Q8)	16; 5; 0 – 76	18; 3; 0 – 63	19; 13; 0 – 76	ns
Swelling, 3rd day after (Q10)	10; 4; 0 – 48	10; 4; 0 – 48	10; 3; 0 – 45	ns
Swelling, 4th day after (Q15)	7; 4; 0 – 35	8; 3; 0 – 35	6; 4; 0 – 29	ns
Swelling, 5th day after (Q16)	5; 4; 0 – 34	6; 3; 0 – 26	5; 4; 0 – 34	ns
Swelling, 6th day after (Q17)	4; 3; 0 – 34	4; 4; 0 – 13	5; 4; 0 – 34	ns
Swelling, 7th day after (Q18)	4; 3; 0 – 31	3; 3; 0 – 10	5; 3; 0 – 31	ns
Bleeding, 1st day after (Q6)	17; 3; 0 – 100	13; 3; 0 – 94	20; 3; 0 – 100	ns

* Wilcoxon's test (α=5%); ns=non-significant.

Patients from both treatment groups scored mild pain two-to-three hours after surgery with a peak of pain just after cessation of the analgesic effect. Pain scores decreased continuously up till the third postoperative day, but this was statistically significant only for the CR group ($p<0.01$, Friedman test). Considering the pooled data (both groups together), the decrease in pain was statistically significant ($p<0.01$, Friedman test) from the cessation of the analgesic effect to the first, second, and third postoperative day. The decrease in pain from the first to the third postoperative day was also statistically significant.

Swelling peaked on the day after the surgery and decreased up to the seventh postoperative day, but this was statistically significant only for the IR group ($p<0.05$, Friedman test). Considering the pooled data, the decrease was statistically significant ($p<0.01$, Friedman test) from the first to the third, fourth, fifth, sixth, and seventh postoperative day, showing a continuous decrease over the time period. Bleeding on the first postoperative day was low for both groups.

There was no statistically significant correlation between treatment time and VAS scores for pain, bleeding and swelling. Ten patients needed additional medication (three

Table 3. *Frequency of positive and negative answers to dichotomous questions. The numbers represent the answers (yes / no).*

Parameter	Total	Inter-group analysis		
		IR	CR	P value*
Need of additional medication (Q11)	10 / 14	3 / 9	7 / 5	ns
Inability to work (Q12)	5 / 19	2 / 10	3 / 9	ns
Need to call a dentist or doctor (Q13)	1 / 23	0 / 12	1 /11	ns
Need of additional treatment (Q14)	0 / 24	0 / 12	0 / 12	ns

* Fisher's exact test (α = 5%); ns=non-significant.

from IR, and seven from CR). They were prescribed analgesics (Paracetamol 500 mg, every 6 hours, for two days). Five patients (two from IR, and three from CR) reported inability to work, and the absent time ranged from 1 to 3 days. Only one patient from the CR group needed to call his dentist for an extra appointment during the first four days post-surgery, but no additional treatment was needed.

Discussion

This study showed that immediate restoration of the tooth crown in connection with implant placement logically demands a longer treatment time than when the tooth is mounted at a later occasion. The mean treatment time in the IR group (about one hour) was almost twice as long as in the CR group, from which it may be deduced that the implant placement procedure and the prosthetic procedures took almost the same amount of time. One of the first points to be considered based on this information is that the risks of infection may be directly related to the duration of the treatment [10]. Therefore, the importance of using non-traumatic techniques must be emphasized, and antibiotic coverage following the surgical procedure is usually recommended [10]. The duration of the procedure is moreover important information to be given to the patient before the treatment is initiated. According to Hashem et al. [11], preoperative stress and anxiety are factors that may potentially increase the perception of pain during and after surgical procedures. On the other hand, others found that no additional patient satisfaction was obtained by giving extra information on the procedure to the patient before surgery (considering lower third molar extraction) [12]. In our study patients expressed a high degree of satisfaction with the information provided before and after treatment. It is important to emphasize that we evaluated satisfaction based on the patient's opinion regarding the information he or she had received before and after surgery, and not based on the treatment outcome (e.g. esthetics).

No other studies seem to have assessed the difference in treatment time and the patients' perception of treatment discomfort after implant installation with and without immediate mounting of the tooth crown. Considering changes over time, pain and swelling decreased continuously, while bleeding achieved low values when evaluated at the first postoperative day. Only one previous study performed a similar evaluation regarding immediate placement of single implants and found that pain peaked between five and six hours postoperatively, reaching an average of 25 on a 100 mm VAS scale [7]. Similar values were found in our study where the patients' pain scores peaked just after the cessation of the effect of the analgesics, two to three hours after surgery for both treatment groups. This pain level was interpreted as "mild" pain according to the NIH Numerical Rating Scale [11]. Pain scores decreased continuously up till the third postoperative day, also according to what was previously found in the literature. Other studies have investigated postoperative pain after non-immediate implant placement. Based on the NIH Numerical Rating Scale, these studies stated that pain following implant placement ranged from mild to moderate [13,14], scoring between three and five on a 100 mm VAS. In both studies, the peak of pain perception occurred on day one following surgery. Karabuda et al. [13] investigated the analgesic and anti-inflammatory efficacy of two non-steroidal anti-inflammatory drugs (tenoxicam and meloxicam) following dental implant surgery and found pain scores higher than 4 for more than 50% of treated patients in the first twenty-four hours after surgery, independent of which anti-inflammatory drug was used. In our study, on the second day after surgery, more than 70% of the patients (considering both groups) reported pain scores lower than 4, and stopped using rescue analgesics.

Regarding swelling, the scores were similar in the two groups at all-time points, and both groups scored mild swelling from the fourth to the seventh day. Swelling peaked on the day after the surgery and decreased up to the seventh postoperative day. This is not in total agreement with previous studies, since, contrary to pain, swelling seems to reach its maximum one or two days postoperatively [4,7,14]. It has been stated that implant placement caused more severe inflammation when the procedure involved the posterior regions of the jaws [7,14,15], but this was not evaluated in our study since sample size was too small to assess each region separately.

Bleeding on the first postoperative day was low and statistically equal between the groups. There was no statistically significant correlation between treatment time and VAS scores for any of the evaluated parameters. The same can be stated for the need for additional medication and the inability to work. A major pitfall in this case is the fact that a definite view of postoperative pain could only be obtained by instructing patients not to take analgesics postoperatively, but this would be unethical, and would not simulate the real-life pathway patients follow after surgery. Compliance with a regime of non-use of analgesics would probably be poor, further compromising the results [15]. Besides, the fact that the patients were asked to record every evening the worst condition they experienced during the day must also be acknowledged.

In this study, patient's satisfaction with the treatment outcome was not assessed. Although more time consuming, the fact that the patients from the IR group left the operating

room already wearing a fixed prosthesis might influence their behavior, and therefore their sensation of discomfort after surgery. Schropp et al. [17] showed a higher patient satisfaction level following delayed-immediate (10 days postoperatively) prosthesis installation than for delayed prosthesis in single-implant patients. Another study also referred to the higher satisfaction and comfort achieved after immediate restoration [18], but the impact of these high satisfaction levels on perception of pain has yet to be estimated.

Data from this study can be used to inform patients before and during the initial phase of implant treatment. Information on the procedures they are about to undergo can create realistic expectations in patients considering implant placement. Well-informed patients who actively participate in treatment decisions may be more satisfied, independent of outcomes, benefiting both patients and surgeons [11]. Our results also improve the understanding on the impact of single-implant placement for patient's life, both socially and economically (considering days of absence from work and the additional costs for an extra visit to the dentist regarding the tooth restoration). This information should be taken into consideration when the social and economic impact of dental implant surgery is evaluated.

Conclusions

The longer treatment time found for patients treated with immediate tooth restoration following single-implant placement did not increase patients' perception of pain, bleeding and swelling, compared to patients treated with conventional restoration.

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Contributions of each author

RSN helped designing the study, performed the statistical evaluation, and carried out the editing of the manuscript. AEFP helped designing the study, collected the data, and helped in the statistical evaluation. AW helped organizing data and planning the statistical evaluation, as well as gave substantial input to the manuscript editing. CES participated in all of the phases described above.

Conflict of Interest

The authors also state that there are no conflicts of interest to be disclosed.

References

1. Calandriello R, Tomatis M, Vallone R, Rangert B, Gottlow J. Immediate occlusal loading of single lower molars using Branemark System Wide-Platform TiUnite implants: an interim report of a prospective open-ended clinical multicenter study. *Clinical Implant Dentistry and Related Research.* 2003; **5:** 74-80.

2. Gallucci GO, Benic GI, Eckert SE, Papaspyridakos P, Schimmel M, Schrott A, Weber HP. Consensus Statements and Clinical Recommendations for Implant Loading Protocols. *International Journal of Oral and Maxillofacial Implants* 2013; **24:** 180-183.

3. Pontes AE, Ribeiro FS, da Silva VC, Margonar R, Piattelli A, Cirelli JA, Marcantonio E Jr. Clinical and radiographic changes around dental implants inserted in different levels in relation to the crestal bone, under different restoration protocols, in the dog model. *Journal Periodontology*. 2008; **79:** 486-494.

4. Penarrocha M, Garcia B, Marti E, Balager J. Pain and inflammation after periapical surgery in 60 patients. *Journal of Oral and Maxillofacial Surgery.* 2006; **64:** 429-433.

5. Christiansen R, Kirkevang LL, Hørsted-Bindslev P, Wenzel A. Patient discomfort following periapical surgery. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontics* 2008; **105:** 245-250.

6. Tsesis I, Fuss Z, Lin S, Tilinger G, Peled M. Analysis of postoperative symptoms following surgical endodontic treatment. *Quintessence International*. 2003; **34:** 756-760.

7. Urban T, Wenzel A. Discomfort experienced after immediate implant placement associated with three different regenerative techniques. *Clinical Oral Implants Research*. 2010; **21**: 1271-1277.

8. Ainamo J, Bay I. Problems and proposals for recording gingivitis and plaque. *International Dental Journal*. 1975; **25:** 229-235.

9. Mühlemann HR, Son S. Gingival sulcus bleeding - a leading symptom in initial gingivitis. *Helvetica Odontologica Acta.* 1971; **15:** 107-113.

10. Rider CA. Infection control within the oral surgeon's office. *Compendium of Continued Education in Dentistry.* 2004; **25:** 529-533.

11. Hashem AA, Claffey NM, O'Connell B. Pain and anxiety following the placement of dental implants. *International Journal of Oral and Maxillofacial Implants*. 2006; **21:** 943-950.

12. Christensen J, Matzen LH, Wenzel A. Effect of explaining radiographic information to the patient before third molar surgery. *Dentomaxillofacial Radiology.* 2010; **39:** 176-178.

13. Karabuda ZC, Bolukbasi N, Aral A, Basegmez-Zeren C, Ozdemir T. Comparison of analgesic and anti-inflammatory efficacy of selective and non-selective cyclooxygenase-2 inhibitors in dental implant surgery. *Journal of Periodontology.* 2007; **78:** 2284-2288.

14. Gonzalez-Santana H, Penarrocha-Diago M, Guarinos-Carbo J, Balaguer-Martínez J. Pain and inflammation in 41 patients following the placement of 131 dental implants. *Medicina Oral Patologia Oral y Cirurgia Bucal.* 2005; **10:** 258-263.

15. Al-Khabbaz AK, Griffin TJ, Al-Shammari KF. Assessment of pain associated with the surgical placement of dental implants. *Journal of Periodontology.* 2007; **78:** 239-246.

16. Jin J, Sklar GE, Min-Sen-Oh V, Li CS. Factors affecting therapeutic compliance: A review from the patient's perspective. *Therapeutics and Clinical Risk Management*. 2008; **4:** 269-286.

17. Schropp L, Isidor F, Kostopoulos L, Wenzel A. Patient experience of, and satisfaction with, delayed-immediate vs. delayed single-tooth implant placement. *Clinical Oral Implants Research*. 2004; **15**: 498-503.

18. Sârbu I. The immediate insertion, loading and provisional prosthetic restoration of dental implants. *Journal of Medicine and Life*. 2008; **1**: 218-227.