

PAIN FACTORS RELATED TO DENTAL IMPLANT SURGERY: A 7-DAY OBSERVATIONAL CLINICAL STUDY

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Abstract

This article aims to associate patient-reported pain intensity in the immediate seven days after dental implant surgery with surgical factors, sex and patient age. The sample was composed of 108 patients from a dental school in southern Brazilian, between 2018 and 2020. The variables torque, pre- and postoperative medication, healing of first and second intention, gender, age, number of quadrants, number of implants and type of surgery were related to the outcome pain. Pain was reported every day by the patient until the seventh day after surgery, using a visual analogic scale (VAS). Univariate Poisson regression models were used to assess the relationship among pain and the factors. Rate ratios were obtained with 95% of confidence intervals. Overall pain was reported as moderate/intense (VAS: 3-10) by 30.56% of patients, mild pain (VAS: 1-3) by 55.56%, and no pain symptoms were reported by 13.89% of patients. Individuals which the implants were installed with high torques (50-80 N) showed more pain ($p=0.03$) compared to patients which the implants were installed with regular torque (30-45 N). The other factors evaluated were not significant. The torque was the most relevant factor related to pain among the evaluated by the study. High torque generates more postoperative pain than lower torque. The factors gender, age, number of operated quadrants, number of installed implants, type of surgery and pre and postoperative analgesic did not interfere in the patient's pain during the first week after surgery.

Keywords: Dental Implants. Pain. Torque. VAS.

1. Introduction

The implant installation protocols and the osseointegration process have been studied since the first reports of this type of rehabilitation by Bränemark (Branemark 1983; Anusavice et al. 2013). Despite the great advances in macrogeometry, surface treatment and prosthetic connection of implants, there is still a gap when it comes to pain control after implant installation. Even though, postoperative management to minimize the patient's pain is a topic of some studies (Eli et al. 2003; Misch et al. 2008; Scarano et al. 2011; Kim et al. 2013; Sakka and Hanouneh 2013; Mei et al. 2016).

Several factors may be related to individual's postoperative pain. The patient's own pain threshold, besides the oedema, surgical complications, healing process, suture conditions, among others, are cited in the literature (Scarano and Quaranta 1997; Misch et al. 2008; Andrade 2014; Piattelli et al. 2015; Meta et al. 2017). Generally postoperative pain and oedema are managed with non-steroidal anti-inflammatory

drugs (NSAIDs) alone, or steroidal anti-inflammatory drugs (SAIDs), known as corticoids, or by combining NSAIDs and corticoids (Sotto-Maior et al. 2001; Kim et al. 2009; Meta et al. 2017).

Some surgical factors such as the number of quadrants operated on, the number of implants, and the technique employed by the surgeon can influence the reported pain (Kim et al. 2013; Mei et al. 2016). According to some studies (Dao and Leresche 2000; Canakçi and Canakçi 2007; Kim et al. 2013), sex and age are determinant for the pain: female and older individuals are more sensitive to pain.

The ideal implant installation torque is between 30 and 40 Newtons (N) (Vanden Bogaerde 2004). High torque values may be related to an increase in pain manifestation, due to a greater compression that promotes bone ischemia around the implants (Scarano et al. 2011).

The information about the level of pain after surgical procedures and the factors associated with it assist in the expectations created by the patients, increasing their confidence in the professional (Mei et al. 2016). Thus, the aim of the present study is to evaluate the intensity of patient-reported pain during the seven days after dental implant surgery, and associate to surgical factors, gender and age.

2. Material and Methods

The ethics and research committee of the University involved in the study approved this Clinical Observational Cohort Study (n° 2.660.296). All eligible patients were informed of the study objectives, risks and benefits associated with the experimental procedures and those who agreed to participate signed an informed consent form. Those who did not accept to participate were not harmed and followed the treatment. The methodology follows the STROBE observational study criteria.

Participants

The participants were male and female patients, with 18 years old or older, who sought dental replacement at a school of dentistry in southern Brazil, between 2018 and 2020. Residents, under the supervision of an Implant Dentistry professor, performed the surgeries.

Inclusion criteria

The inclusion criteria were: partial or total dental absence; good oral health; no active cavities, residual roots, periapical or periodontal infections; blood tests (blood count, coagulogram, fasting blood glucose, serum vitamin D); good general state of health, in cases of diabetes and hypertension, these should be controlled; the patient signed a term of free, informed consent. Individuals who did not meet these criteria were automatically excluded.

Pre-operative procedures

A complete clinical examination was performed and blood and imaging exams were requested for all individuals. Periapical, panoramic and/or computed tomography radiographs were used, according to the needs of the case, to guide the surgeon on regarding the selection of the size and diameter of the dental implant. At this stage, the individual's personal information (age, sex, and general health status) were recorded in a patient file, based on questionnaires and complementary laboratory tests.

The preoperative medication prescribed for all patients was amoxicillin 500mg (2 capsules 1 hour before the procedure), and paracetamol 750mg (1 tablet 1 hour before the procedure) (Shirvani et al. 2016; Kim and Seo 2020). Azithromycin 500mg was prescribed in situations where the patient was allergic to penicillin (four patients). No patient was allergic to paracetamol.

Surgical procedures

There was no intervention of the researchers in the type of treatment and management selected by the surgeons. The dental implants used in the study were Cone Morse (CM) and External Hexagon (EH)

implants from Signo Vinces (Campo Largo, PR, Brazil), Neodent (Curitiba, PR, Brazil), Conexão (Arujá, SP, Brazil), or SIN (São Paulo, SP, Brazil). The implantodontist chose the implant diameter according to the case. Two trained students were responsible for the data tabulation (torque, type of suture, region of the implant, patient's age, gender, implant specifications and possible complications). Immediately after implant installation, the platforms were covered with cover screws, healing screws, or immediate provisional.

The postoperative medication prescribed for all patients was:

Analgesic: Paracetamol 750mg, 1 tablet every 6 h for 3 days.

Anti-inflammatory:

Regimen 1 (NSAID) - Ibuprofen 600mg, 1 tablet every 8h for 3 days;

Regime 2 (SAID) - Dexamethasone 4mg, 1 tablet a day for 3 days;

The researchers did not interfere in the selection of anti-inflammatory regimen. Antibiotic was prescribed according to the surgeon choice (patient need). No patients were allergic to anti-inflammatory regimens.

Post-operative assessment

After the implant installation, the patient received a Visual Analogue Scale (VAS) and was instructed to write down the threshold of pain on the day of the surgery, and in the next six postoperative days, always before going to sleep.

Seven days after the surgery, the patients returned for remove the suture, evaluate the healing (first or second intention) and return the Visual Analogue Scale.

Assessment of healing

The assessment of healing by first and second intention was performed by visual examination (clinical inspection) by two evaluators, both calibrated by Kappa test (Evaluator 1: kappa=0.88; Evaluator 2: kappa=0.65). If the flap edges were approximated, with linear healing, without loss of tissue and without the presence of exudate, the healing was characterised as of first intention. If the flap edges were not in contact, and the space present was filled by granulation tissue, with a significant loss of tissue, the healing was characterised as of second intention.

Predictor variables

Sex: Female or Male. Age: 24 to 50 years; 51 to 58 years; 59 to 78 years.

Number of implants: One implant; Two implants; Three or more implants.

Number of quadrants: One quadrant operated; Two quadrants; Three or four quadrants.

Type of surgery: Normal (only the implants installation surgery); Complex (tooth extraction and/or maxillary sinus lift and/or bone graft + implant installation).

Implant installation torque: 0 - 25N (low); 30N to 45N (regular); 50N to 80N (high).

Healing: First intention (approximate flap edges); Second intention (the edges of the flap were not in contact).

Analgesic: Yes – used; No – did not use. Anti-inflammatory: NSAID; Dexamethasone; Did not use.

Patients who did not take the analgesic and/or the anti-inflammatory (even with the prescription) were not excluded from the study. The data treatment considered this variable.

All study variables were recorded, at the day of the implant installation and after 7 days. Data was converted into an electronic database.

Outcome

The outcome of this study was the presence and intensity of postoperative pain, the instrument used to assess the outcome of the study was a visual analogue scale (VAS): a 10-mm horizontal plane,

numbered from 0 (zero) to 10 (ten), where 0 indicates "no pain" and 10 "the worst imaginable pain". Data of the outcome variable (pain) were analysed as an average of the pain of all postoperative days (day of surgery until the seventh postoperative day).

Statistical Methods

Data were computed in Excel 16.0 (Microsoft Corporation, Redmond, USA) in descriptive form, presenting absolute and relative values of the variables and outcome. The relationship among pain and the predictors was performed using univariate Poisson regression models, where each variable was analysed separately. Rate ratios were obtained with 95% confidence intervals. Pain values were grouped in moderate/intense (VAS: 3-10), mild (VAS: 1-3) and no pain (VAS: 0).

3. Results

One hundred and eight patients were evaluated in the study, 42 (38.9%) males and 66 (61.1%) females. Six individuals did not fill the VAS and were excluded from the study. The mean age of the patients was 54 years. The oldest patient was 78.3 years old and the youngest patient was 24 years old. The most frequent torque observed was 30-45N. Overall pain was reported as moderate/intense (VAS: 3-10) by 33 patients (30.56%), mild pain (VAS: 1-3) by 60 patients (55.56%) and no pain symptoms were reported by 15 patients (13.89%). The other study variables are described in Table 1. The overall distribution of individuals according to pain on each day is described in Table 2.

Table 1. Distribution of individuals according to the study variables (N= 108).

	Total n (%)	Pain (Sum of 7 postoperative days) n (%)		
		No pain	Mild	Moderate/Intense
<i>Gender</i>				
Male	42 (38.9)	7 (16.7)	26 (61.9)	9 (21)
Female	66 (61.1)	8 (12.1)	34 (51.5)	24 (36.4)
<i>Age (tertile)</i>				
24 a 50	36 (33)	4 (11.1)	21 (58.3)	11 (30.6)
51 a 58	37 (34)	7 (18.9)	23 (62.1)	7 (18.9)
59 a 78	35 (32)	4 (11.4)	16 (45.7)	15 (42.9)
<i>Number of implants</i>				
1	38 (35)	8 (21)	19 (50)	11 (28.9)
2	42 (38)	5 (11.9)	24 (57.1)	13 (30.9)
3 or more	28 (25)	2 (7.1)	17 (60.7)	9 (32.1)
<i>Number of quadrants</i>				
1	51 (47)	9 (17.6)	25 (49)	17 (33.3)
2	53 (49.1)	5 (9.4)	33 (62.3)	15 (28.3)
3	4 (3.7)	1 (25)	2 (50)	1 (25)
<i>Type of surgery</i>				
Normal	84 (82.3)	12 (14.2)	47 (55.9)	25 (29.8)
Complex	18 (17.6)	2 (11.1)	11 (61.1)	5 (27.8)
<i>Torque</i>				
0-25 N	14 (12.9)	3 (21.4)	7 (50)	4 (28.6)
30-45N	49 (45.4)	9 (18.4)	29 (59.2)	11 (22.4)
50-80N	45 (41.7)	3 (6.7)	24 (53.3)	18 (40)
<i>Healing</i>				
1 st intention	89 (84.8)	12 (13.5)	54 (60.7)	23 (25.8)
2 nd intention	16 (15.2)	3 (18.7)	5 (31.2)	8 (50)

Table 1. Continued.

<i>Post-operation medication</i>				
<i>Analgesic</i>				
Took	98 (90.7)	14 (14.3)	54 (55.1)	30 (30.6)
Not taken	10 (9.3)	1 (10)	6 (60)	3 (30)
<i>Anti-inflammatory</i>				
NSAID	90 (83.3)	12 (10.8)	52 (46.8)	26 (23.4)
Dexamethasone	15 (13.9)	3 (20.0)	8 (53.3)	4 (26.7)
Not taken	3 (2.8)	0 (0.0)	0 (0.0)	30 (100.0)

Table 2. Distribution of individuals according to the level of pain each day (N=108).

Pain/ day	n (%)
<i>Day of surgery</i>	
No pain	16 (14.8)
Mild (1-3)	36 (33.3)
Moderate (4-6)	29 (26.8)
Intense (8-10)	27 (25)
<i>First day after surgery</i>	
No pain	19 (17.6)
Mild (1-3)	52 (48.1)
Moderate (4-6)	24 (22.2)
Intense (8-10)	13 (12)
<i>Second day after surgery</i>	
No pain	25 (23.1)
Mild (1-3)	56 (51.8)
Moderate (4-6)	17 (15.7)
Intense (8-10)	10 (9.3)
<i>Third day after surgery</i>	
No pain	31 (28)
Mild (1-3)	52 (48.1)
Moderate (4-6)	16 (14.8)
Intense (8-10)	9 (8.3)
<i>Fourth day after surgery</i>	
No pain	42 (38.9)
Mild (1-3)	49 (45.4)
Moderate (4-6)	11 (10.2)
Intense (8-10)	6 (5.6)
<i>Fifth day after surgery</i>	
No pain	43 (40.2)
Mild (1-3)	49 (45.6)
Moderate (4-6)	9 (8.4)
Intense (8-10)	6 (5.6)
<i>Sixth day after surgery</i>	
No pain	47 (44.8)
Mild (1-3)	47 (44.8)
Moderate (4-6)	4 (3.8)
Intense (8-10)	7 (6.7)
<i>General pain</i>	
No pain	15 (13.9)
Mild (1-3)	60 (55.6)
Moderate/ Intense (3-10)	33 (30.6)
<i>Pain patients</i>	
	93 (86.1)
<i>Painless patients</i>	
	15 (13.9)

Table 3 shows the univariate Poisson regression analysis. Implants installed with high torque (50-80 N) generated higher pain scores ($p=0.03$) compared to implants installed with regular torque (30-45 N) and low torque (0-25 N).

Table 3. Univariate Poisson regression analysis of the sum of pain at 7 days after surgery (N=108).

Variable	RR (95% IC)	p-value
Sex (ref=Female)		
Male	0.84 (0.68– 1.05)	0.12
Age (ref=24-50)		
51-58	0.84 (0.64-1.09)	0.18
59-78	1.10 (0.86 -1.39)	0.43
Number of implants (ref=1)		
2	1.10 (0.85-1.43)	0.46
3 or more	1.16 (0.88-1.52)	0.28
Number of quadrants (ref=1)		
2	1.02 (0.83 -1.27)	0.80
3	0.86 (0.42 -1.77)	0.69
Type of surgery (ref=normal)		
Complex	1.01 (0.77-1.32)	0.94
Torque (ref=30-45)		
0-25	1.03 (0.70-1.51)	0.88
50-80	1.29 (1.03-1.59)	0.03
Healing (ref= ^{1st} intention)		
2 nd Intention	1.17 (0.86-1.60)	0.32
Analgesic (ref=no)		
Yes	0.97 (0.70 –1.35)	0.85
Anti-inflammatory (ref=NSAID)		
Dexamethasone	0.92 (0.65-1.30)	0.64
Did not use	1.73 (1.54- 1.94)	0.01

TE= tooth extraction; MSL= maxillary sinus lift.

Low torque (0-25N) showed no difference in pain threshold compared to regular torque. The highest peak of pain was observed on the second postoperative day with high torque compared to low and regular torques (Figure 1). Patients who did not take anti-inflammatory drugs had more pain ($p=0.01$) compared to the patients that used the drug regimens.

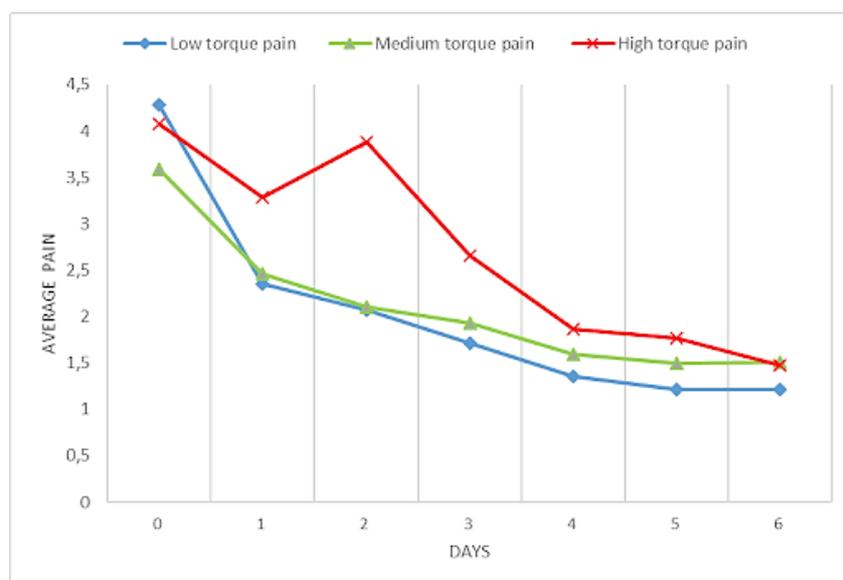


Figure 1. Average pain on different days according to the torque.

The healing process did not show statistical significance. There was only a trend shown in the figure 2, where patients with healing by second intention presented higher numerical average on all days.

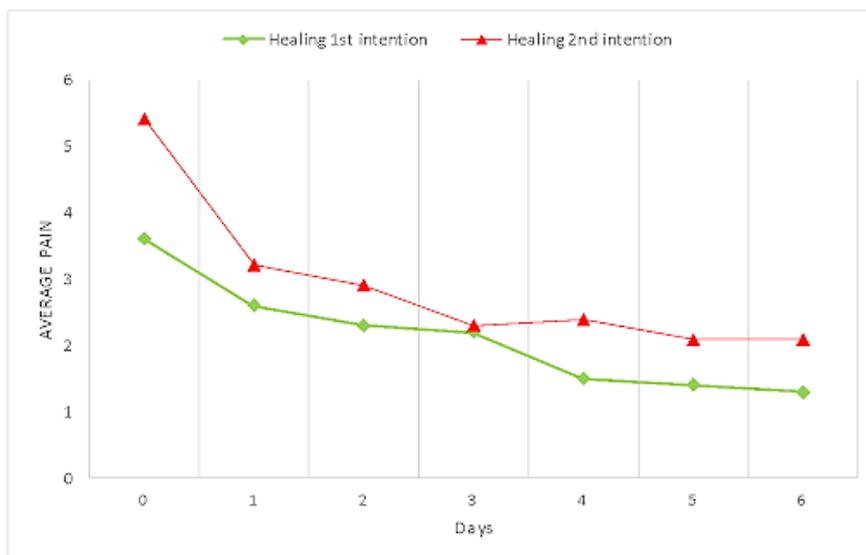


Figure 2. Average pain according to healing.

4. Discussion

The present study evaluated the intensity of patient-reported pain after the installation of dental implants, and associated it with surgical factors, gender and age. With 108 observations, it was verified that torque is the most important factor related to pain, among all the factors evaluated. High torques (50-80N) resulted in higher pain scores at the seven postoperative days, with a significant increase on the pain on the second day, compared to low (0-25N) and regular (30-45N) torques. Figure 1 shows that high torques are related to greater pain between the days 1 (one day after surgery) and 3 (three days after surgery). This contrast is not so evident on other situations. Except of the second day for high torque, there was a decrease in pain throughout the week. In the 24 hours after surgery, the patient is still under the effect of the anaesthesia (Kim et al. 2013). On the second postoperative day, the oedema reaches the peak, which may justify the increased perception of pain by patients with high torque. After it, inflammation begins to gradually regress until the 5th postoperative day, which justifies the decline in pain perception by patients (Al-Shamiri et al. 2017).

Tissue regeneration is a coordinated process controlled by different types of cells that communicate via cytokines, growth factors and extracellular matrix molecules (Bosshardt et al. 2017). With high torques, the growth of capillaries for bone formation is slowed down, leading to a decrease in vascularisation at the bone/implant interface (Checa and Prendergast 2010). This reduction may result in pressure necrosis, which may be associated with increased pain (Scarano et al. 2011). Other experiments have also related torque with pain (Scarano et al. 2011; Cannizzaro et al. 2012; Mundt et al. 2016). However, they do not assess the other factors addressed by the present study. Thus, for the first time, one study demonstrated that the torque factor is more relevant for the pain outcome than number of implants, number of quadrants, type of healing, among others already mentioned.

Patients who did not take the anti-inflammatory regimen presented more pain. However, the low number of this occurrence (n=3) does not allow conclusions about it. A previous study by Bahamman et al. (2016) highlights the reduction in postoperative pain induced by ibuprofen (600mg, 1 hour before surgery and 6 hours after) and dexamethasone (4mg, 1 hour before surgery and 6 hours after). Agents such as NSAIDs suppress the cyclooxygenase pathway, while glucocorticoids such as dexamethasone act by inhibiting phospholipase A₂ activity (Kim et al. 2009). Regarding the analgesic regimen used in the present study, no statistical difference ($p=0.28$) was found in the presence and intensity of pain reported by patients taking and not taking the protocol. These findings agree with the systematic review and meta-analysis by Shirvani et al. (2016), where the efficacy of a single dose of paracetamol before local anaesthesia was tested for treatment of irreversible pulpitis. The study found no relevance of paracetamol use before the procedure. Since only 10 patients did not take the indicated analgesic regimen, our data

should be evaluated with caution. Another review (Bailey et al. 2014) indicates that ibuprofen 400mg is superior to paracetamol 1000mg for of analgesia when used for pain relief after lower third molar extraction.

Patients who had healing by second intention showed the same pain threshold as patients with healing by first intention. 84.8% of the patients had healing by first intention, which is a positive point of the surgeries of the study. Bone healing around implants follows a sequence of intramembranous osteogenesis starting with tissue bone formation, followed by parallel fibre formation and lamellar bone surrounding the bone-implant interface (Bosshardt et al. 2017). Surgical trauma, overheating during surgery and the onset of a post-surgical peri-implant infection at both bone and soft tissue levels are important reasons for failures (Piattelli et al. 1997; Misch et al. 2008). In this study, healing was verified by visual/clinical inspection seven days after de surgery.

This study did not show significance for the variables age and gender. In a previous study, patients younger than 35 years old had lower pain threshold compared to individuals with more than 35 years old (Nazir 2018). Studies show that the pain threshold is intensified by age due to the decrease in blood flow, fatty alterations of bone tissue alterations (Canakçi and Canakçi 2007; Kim et al. 2013). The association of gender and pain is also inconclusive. Bastos et al. (2008) showed that females reported more intense pain, justified by the fact that women are more likely to express their emotions and thoughts more freely than men (Dao and Leresche 2000; Kim et al. 2013).

Increasing the number of quadrants and implants did not result in more pain. The results of the present study disagree with a similar observational study (Kim et al. 2013) where pain scores were lower in patients with one implant compared to patients with two implants. Although the pain outcome is subjective, the visual analogue scale is a well-established procedure. The participants of this study filled in the scale daily, always at the same time. Despite being quite instructed for the filling process, the participant's dependence was a limitation of the present study.

5. Conclusions

Torque is the most important factor related to pain among all the factors evaluated. High torque generates more postoperative pain than regular torque. The factors gender, age, number of quadrants, number of implants, type of surgery and analgesic did not interfere on the patient's pain during the first week after the surgery.

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Ethics Approval: The ethics and research committee of the University involved in the study approved this Clinical Observational Cohort Study (n ° 2.660.296).

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