Short-term postoperative discomfort in patients receiving flapless contra open implant surgery

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ABSTRACT

Purpose: The aim of this pilot study was to evaluate subjective and objective findings on short-term postoperative discomfort in patients receiving flapless implant surgery compared to traditional open flap surgery. Materials and Methods: A two-centre, prospective survey study was conducted, using a customized questionnaire. Between December 2010 and January 2012, 20 patients were consecutively included. Eleven received conventional open-flap surgery and nine received flapless surgery. Inflammatory signs, analgesic consumption and sleeping difficulties were evaluated up to seven days postoperatively. A clinical examination was made one week postoperatively. Results: Significantly less experienced swelling was noted 24 hours after flapless surgery compared to open flap surgery for patients receiving four implants or more, and at three days postoperatively for patients receiving single implants. No difference concerning sleeping difficulties, pain or analgesic consumption was found. Clinical examination one week postoperatively showed no differences in wound gaps, redness of the mucosa, or presence of pus between the groups. Conclusions: In conclusion, flapless surgery seems to have a limited effect on postoperative comfort and short-term postoperative signs of soft tissue healing compared to open flap surgery. There is a need for larger randomized trials for evaluating differences in postoperative discomfort between the two surgical techniques.

Keywords: Postoperative Discomfort; Flapless Surgery; Guided Implant Surgery

1. INTRODUCTION

To enable the insertion of a dental implant, open flap

surgery has been a standard technique. Conventional implant surgery involves transmucosal incision and reflection of a mucoperiosteal flap, followed by preparation of an implant socket in the alveolar bone. A dental implant can then be inserted and the flap can be sutured back into its original position [1]. However, this method can lead to some post-operative discomforts. Both physical and mental strains are commonly associated with conventional implant surgery [2-4]. Inflammatory signs such as pain, swelling and bleeding are normally seen postoperatively [5].

An alternative to a conventional flap elevation is the minimally invasive, flapless approach. Clinical studies have revealed that implants can be successfully placed with a flapless technique [6-9]. The treatment time and patient discomforts are reduced compared to traditional implant surgery [8,10,11]. Blood supply to the periosteum is preserved and sutures become superfluous [5,12, 13]. A histological study has shown significantly higher amount of blood vessels in the peri-implant mucosa three months after insertion of a dental implant in flapless surgery compared to flap elevation. Furthermore, no signs of inflammation in the mucosa surrounding such implants were seen [14].

Flapless surgery is an advanced technique that requires considerable surgical experience and extensive knowledge of the underlying tissue anatomy [15]. The main disadvantages are the inability to visualize anatomic landmarks, increased risk of misplaced implants, risk of over heating and the impossibility to manipulate the soft tissue [5,15].

To overcome some of the problems encountered in flapless surgery, a 3D planning software [16], based on a *cone beam computed tomography* (CBCT) or regular *computed tomography* (CT) scan, has been developed. This method has been defined as computer-assisted surgery and includes the use of a surgical template [5,17].



Current studies on computer-assisted surgery show a high level of implant survival (91% - 100%) after 12 - 60 months [18], but there are no long-term follow-ups [17]. The accuracy of the available systems has not yet been perfected [18]. An *in vitro* study has shown an increased heat generation during drilling when a surgical template is used [19].

There is a need of further research in post-operative comfort associated with flapless and computer guided implant surgery [17]. Computer-assisted surgery is still considered to be an experimental treatment and constitutes an increased cost for the patient. It is therefore desirable to further investigate what the benefits are at a patient level.

The aim of this pilot study was to evaluate subjective and objective findings on short-term postoperative discomfort in patients receiving flapless implant surgery compared to traditional open surgery. The working hypothesis was that using flapless technique leads to less short-term postoperative discomfort.

2. METHODS

2.1. Study Design

The study took place from December 2010 to January 2012 at the maxillofacial unit at the Halland Hospital, Halmstad, and in a private clinic specialized in implant dentistry, located in Ytterby, Sweden. One surgeon was an experienced maxillofacial specialist and the other was an experienced DDS with high level of knowledge in implant dentistry.

Patients scheduled for flapless implant surgery who met the inclusion/exclusion criteria (**Table 1**) were asked to participate in the study. These patients were matched with patients referred for conventional open flap implant

Table 1. Inclusion and exclusion criteria.

Inclusion	Exclusion	
Patient \geq 18 years	Implant treatment of the mandible	
Implant treatment is necessary	Direct placement of implant	
Patient consent available	Bone augmentation needed	
	Pregnancy	
	Immunocompromised patient	
	Bleeding disorders	
	Drug or alcohol abuse	
	Radiation of head/neck-region	
	Psychiatric disease	
	Uncontrolled diabetes	
	Completed cytostatic treatment	
	Bisphosphonate treatment	

treatment. They were matched in number of implants and position of implants. Taking part in the study was completely voluntary, anonymous and did not affect the choice of treatment. Informed consent was obtained from all participants. The patient selection was consecutive. The ethical board at the Faculty of Odontology, Malmö University, issued ethical approval.

A total of 20 patients were included in the study (*mean age* 56.9 years, *SD* 18.75). Six patients (*mean age* 51.8 years, *SD* 19.64) received single implants installed with conventional technique and five (*mean age* 40.8 years, *SD* 16.45) received single implants installed with flapless technique. Five patients (*mean age* 68.0 years, *SD* 8.43) received four implants or more installed with conventional technique and four (*mean age* 71.0 years, *SD* 13.21) received four implants or more installed with flapless technique. No significant differences regarding gender and age were seen between the groups.

2.2. Surgical Methods

Computer-assisted implant surgery in this study included the following steps:

A clinical and radiographic examination was made; including panoramic X-ray to ensure the anatomical and pathophysiological conditions of the jaws. Impressions for study casts were taken together with a stable index. A dental technician manufactured working models that were used to make a diagnostic tooth set-up. When the tooth set-up was accepted, a radiographic guide in clear acrylic was made. This guide was provided with radiopaque reference markers. A double CT-scan protocol was used. First the patient was scanned with the radiological guide and index in place. Thereafter, the guide alone was scanned. In the planning software the two scans were overlaid to distinguish soft tissue from the guide material, as they have similar radio-density. Data from the scan was processed in the planning software. Virtual implants were then placed with consideration to anatomical structures as well as depth, angulation and position of the fixture.

The surgical guide was manufactured in hard acrylic with sleeves for the implant drills. The guide was positioned using the original index and stabilized with the help of anchor pins. In this stage, the operator transferred the planned implant position, depth and angle from the software to the actual mouth. To penetrate the mucosa a tissue punch was used.

In this study *NobelClinican*TM solution (*Nobel Biocare*, *Yorba Linda*, *CA*) was used for planning and planning conducted by the operating surgeon. A tissue punch was used for all flapless incisions.

In the open flap surgery group a mucoperiosteal flap was raised to expose the alveolar bone. The implant sockets were prepared and implants installed in accordance to the manufacturers drill protocol. After implant installation the flap was sutured using *Vicryl* 4-0 sutures (*Ethicon Inc., Somerville, NJ*).

Surgery was conducted using local anaesthesia (*Xylocain*[®] *Dental Adrenalin, Dentsply Pharmaceutical*). Prescription-free NSAID and Paracetamol were used for postoperative pain relief when needed. All patients in the trial received antibiotics *per os* according to the clinics standardized protocol.

2.3. Postoperative Evaluation

Patients that agreed to take part in the study received a multiple-choice form. They were asked to evaluate subjective post-operative discomfort and sleeping difficulties 24 hours, three days and seven days postoperatively. Consumption of analgesics was recorded at the same intervals. A numerical rating scale (NRS) was used to evaluate pain (Figure 1).

					Ques	stionna	ire				
1.		I am a:		Woman	L			Man			
2.		I was boi	m 19								
3.		Did you	experien	ce swelli	ng in the	operated	d area 24	hou	rs after surg	ery?	
									No, not at Some swe A lot of sw	lling	
4.		Did you	experien	ce bleedi	ing from	the opera	ated area	24 h	ours after s	urgery?	
									No, not at Some blee A lot of bl	eding	
5.		Rate you	r pain 24	4 hours a	fter the p	orocedure	:				
	<u>0</u> No pain	<u>1</u>	2	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u> Worst pain imaginable
6.		Did you	use any j	pain kille	ers 24 hou	urs after	surgery?				

Yes
 No
 Amount:_____
Type:_____

7. Did you experience difficulty sleeping 24 hours after surgery?

 No, not at all
 Some sleeping difficulties
 Severe sleeping difficulties

Thank you for participating!

Figure 1. Questionnaire used by patient at 24 hours, three and seven days postoperatively in accordance.

All patients were examined 1 week postoperatively by the operating surgeon according to a standardized form (**Figure 2**). Patient and dentist forms were matched using a code system.

2.4. Statistical Methods

Statistical analysis was conducted using SPSS 20.0 (SPSS, Inc., Chicago, IL). Due to the small sample size

Fishers' exact test was used for categorical variables and a non-parametric statistical hypothesis test (*Mann-Whitney U-test*) for numerical variables. Level of significance was set at p < 0.05.

3. RESULTS

3.1. Single Implants

No significant difference in experienced postoperative

Dentist form

This form is filled out by the dentist at the examination one week after surgery. Enter the number from the patient questionnaire in the upper right corner.

1.	Which method was used for implant surgery?	Open flap 🗆 Flapless
2.	Which jaw was treated?	dible 🗆 Both
3.	How many fixtures were installed?	 □ Single implant □ 2-3 fixtures
4.	In which positions were the fixtures placed?	□ More than 4 fixtures
5.	Which type of antibiotic was used and what dose?	
		Туре:
		Dose:
		□ No antibiotics
6.	Wound gaps?	
		 □ <1 mm □ 1-2 mm □ >2 mm
7.	Redness of the mucosa?	
		 □ Less than 25 % of the surgical area □ 25-50 % of the surgical area □ More than 50 % of the surgical area
8.	Presence of pus in the surgical area?	
		□ Yes □ No

Figure 2. Form filled out by dentist one week postoperatively.

swelling was reported between the groups at 24 hours and seven days after installation but at three days a significant difference was noted (p < 0.05, **Table 2**). No differences in NRS scores for pain were seen at any interval (**Table 3**). After 24 hours 2/6 patients in the open flap surgery group and 1/5 patients in the flapless surgery group reported some bleeding. Three and seven days postoperatively no bleeding was reported in any of the groups. No significant differences were seen.

After 24 hours 5/6 patients in the open flap surgery group and 2/5 in the flapless group consumed analgesics. After three days none of the patients consumed analgesics. No significant difference was seen between the groups.

Two out of five patients in the flapless group reported some sleeping difficulties after 24 hours, but none after three and seven days. In the open flap group 1/6 patients reported some sleeping difficulties at 24 hours, after three days 1/6 patients reported some sleeping difficulties and at seven days no patients experienced any sleeping difficulties. No statistical difference was found at any interval. No correlation between level of pain and sleeping difficulties was seen. Two patients reported paresthesia seven days after surgery and both had single implants installed in the anterior region using flap elevation.

Table 2. Swelling.

Method	Swelling 24 h	Swelling 3 days	Swelling 7 days
Flapless [n = 5]	None = 40% [n = 2] Some = 60% [n = 3] A lot = 0% [n = 0]	None = 100% [n = 5] Some = 0% [n = 0] A lot = 0% [n = 0]	None = 100% [n = 5] Some = 0% [n = 0] A lot = 0% [n = 0]
Open flap [n = 6]	None = 0% [n = 0] Some = 66.7% [n = 4] A lot = 33.3% [n = 2]	None = 16.7% [n = 1] Some = 83.3% [n = 5] A lot = 0% [n = 0]	None = 83.3% [n = 5] Some = 16.7% [n = 1] A lot = 0% [n = 0]
<i>p</i> -value	0.212	0.015	1.0

Experienced swelling at different intervals for patients receiving single implants.

Table 3. Pain.

Method	Pain 24 h	Pain 3 days	Pain 7 days
Flapless $[n = 5]$	1 [0-4]	0 [0-2]	0 [0-2]
Open flap [n = 6]	3 [0-7]	0 [0-2]	0 [0-1]
<i>p</i> -value	0.404	0.840	0.521

Median values for pain [NRS] at different intervals [min-max] for patients receiving single implants.

3.2. Four Implants or More

Significant difference between the groups in experienced swelling was reported at 24 hours but not at three or seven days (p < 0.05, **Table 4**). One out of five patients in the open flap group experienced bleeding at 24 hours and at three days. No significant differences were seen between the groups. No differences in NRS scores for pain were seen at any interval (**Table 5**). After 24 hours 4/5 patients in the open flap surgery group and 2/4 in the flapless group consumed analgesics. After three days none of the patients consumed analgesics. Two out of five patients in the open surgery group reported some sleeping difficulties after 24 hours, 1/5 after three days but none after seven days. In the flapless group none of the patients reported sleeping difficulties. No paresthesia was reported at seven days.

3.3. Clinical Examination

Clinical examination one week postoperatively showed no statistical differences in wound gaps, redness of the mucosa or presence of pus between any groups. The majority of the patients had redness of the mucosa <25% of the operated area, wound gaps <1 mm and none had presence of pus.

Table	1	Swel	ling
rabic	т.	0,00	unig.

Method	Swelling 24 h	Swelling 3 days	Swelling 7 days
Flapless [n = 4]	None = 50% [n = 2] Some = 50% [n = 2] A lot = 0% [n = 0]	None = 75% [n = 3] Some = 25% [n = 1] A lot = 0% [n = 0]	None = 75% [n = 3] Some = 25% [n = 1] A lot = 0% [n = 0]
Open flap [n = 5]	None = 0% [n = 0] Some = 20% [n = 1] A lot = 80% [n = 4]	None = 0% [n = 0] Some = 60% [n = 3] A lot = 40% [n = 4]	None = 100% [n = 5] Some = 0% [n = 0] A lot = 0% [n = 0]
<i>p</i> -value	0.048	0.079	0.264

Experienced swelling at different intervals for patients receiving ≥ 4 implants.

Table 5	5. Pain.
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Method	Pain 24 h	Pain 3 days	Pain 7 days
Flapless $[n = 4]$	1 [0-3]	1 [0-2]	0 [0-2]
Open flap $[n = 5]$	4 [1-5]	2 [0-5]	0 [0-1]
<i>p</i> -value	0.59	0.592	0.737

Median values for pain [NRS] at different intervals [min-max] for patients receiving \geq 4 implants.

4. DISCUSSION

In this study a tendency to short-term benefits in postoperative comfort was seen in the flapless surgery group as swelling was significantly less reported in this group. No significant differences could be seen regarding pain or analgesic consumption. These latter findings do not correlate with results reported by Fortin et al., [20] where the patients receiving flapless surgery experienced less pain up to two days and consumed less analgesic up to three days, and Nkenke et al. [21] who found a significant reduction in pain and swelling for patients receiving flapless surgery up to seven days postoperatively. Swelling, in that study, was measured with an optical 3D image system. Different ways to register pain (VAS-scale in the two studies above and NRS in this study) as well as different statistical tests make comparison of the results somewhat uncertain. It cannot be excluded that the small sample size in the present study could have an influence on the divergent findings compared to other studies.

It should also be noted that pain could arise from factors not associated with the surgical method itself, such as surgical time and the patients' fear, stress and anxiety levels [20]. In third molar surgery extended operating time is correlated to increased postoperative pain [21-23] and complications such as paresthesia [24,25]; this might also be valid for implant surgery. In the present study surgical time was not measured, but increased amount of installed implants could be expected to result in extended surgical time. Despite this, pain levels were not significantly higher in patients receiving four implants or more compared to those receiving a single implant. An explanation might be the observation by *Lindeboom et al.* that no gain in time was measured when computer-assisted, flapless surgery was used [26].

Clinical examination one week postoperatively showed no statistical difference in wound gap, redness of the mucosa or presence of pus between groups and the observed changes were discrete, indicating that the advantage of flapless surgery contra open flap surgery for this reason can be questioned.

Patients in this study were allocated into the different groups as they were referred to the clinics. Patients referred for flapless surgery formed one group and patients referred for conventional surgery formed the other group. Patients in both groups were matched according to implant position and number of implants. It would have been desirable to randomize the patients into the two different groups. However, as the patients had to pay an additional cost for (computer-assisted) flapless surgery and not all patients were willing to do this, a randomization was not possible to perform.

In this study 20 patients participated. The low number of individuals can be contributed to the novelty of this treatment method and the higher cost of flapless implant surgery in combination with computer guided surgery. Still, significant differences were found in some areas. It would be desirable to increase the sample size to be able to detect smaller differences and obtain more reliable results.

Two patients in the open flap surgery group [single implant] reported paresthesia one week post-operatively. Temporary paresthesia has been shown to be a relatively common complication following implant surgery, especially in the mandible [27,28]. It can result from poor flap design, performing terminal block of the inferior alveolar nerve and during osteotomy preparation [27]. The paresthesia is often reversible and the incidence reported varies between 6.5% - 36% [28-30]. The sensation often returns within four months and beyond [29]. The use of computer assisted implant surgery in combination with flapless technique may reduce the risk of nerve injury. It is not possible to know if the paresthesias reported in this study are reversible since the follow up time was limited to one week.

All patients in this study received antibiotics nevertheless there is currently no consensus regarding the use of antibiotics in implant dentistry [31] and there are no studies that evaluate the effect of antibiotics on postoperative discomfort in implant surgery. In third molar surgery postoperative pain was not reduced when using antibiotics [32,33].

This study shows that the main advantage of using flapless surgery is less postoperative swelling. This is to be expected since flapless surgery is less traumatizing to the soft tissue. No other benefits were found on a patient level. Still, maintaining blood supply to the periosteum is a major benefit since it potentially minimizes the risk of loosing bone height. The major disadvantages of flapless implant surgery can be avoided by using a computer assisted approach, yet this method also has some weaknesses. These include risk of overheating and inability to visualize anatomical landmarks. Computer assisted implant surgery is also an expensive treatment.

5. CONCLUSION

This pilot study indicates that flapless surgery compared to open flap surgery can lead to less postoperative swelling while no difference is seen regarding pain or postoperative bleeding. However, randomized studies based on larger sample sizes with focus on quality of life effects, including a cost-benefit analysis are required because of the considerably increased cost for the patient receiving flapless surgery.

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