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Laser de diodo de alta potência para cirurgia de segundo estágio de implantes: um ensaio clínico piloto randomizado

High-power diode laser for second-stage implant surgery: a randomized pilot clinical trial

Láser de diodo de alta potencia en la segunda fase quirúrgica de implantes: un ensayo clínico piloto aleatorio

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Resumo

O presente estudo teve como objetivo comparar a técnica convencional com bisturi e o uso de laser de diodo de alta potência para cirurgia de segundo estágio em implantes dentais. Para isso, quinze pacientes foram aleatoriamente designados para receber a técnica convencional com bisturi (Grupo Controle, n = 7) ou uma técnica com uso de laser diodo (Grupo Laser, n = 8) para cirurgia de segundo estágio de implantes submersos instalados ao nível ósseo. A quantidade de anestésico local necessária e o tempo cirúrgico total foram determinados logo após a cirurgia. Dor, característica da mucosa peri-implantar e sangramento foram avaliados no final da cirurgia e após 7 e 15 dias. Também foram coletadas informações sobre a necessidade de drogas analgésicas no pós-operatório no primeiro dia e nas duas semanas seguintes. O tempo cirúrgico foi significativamente menor no Grupo Laser (P = 0,001) e apenas o Grupo Controle apresentou sangramento no final da cirurgia e no sétimo dia (P = <0,001; P = 0,026). As demais avaliações não mostraram diferenças entre os grupos. Dentro das limitações do presente estudo piloto e em comparação com os resultados clínicos da técnica convencional com bisturi, o uso do laser diodo de alta potência parece ser relativamente mais vantajoso para a cirurgia de segundo estágio de implantes dentais.

Palavras-chave: Implantes dentários; Lasers; Cirurgia oral.

Abstract

The present study aimed to compare the conventional scalpel technique and the use of a high-power diode laser for second-stage implant surgery. For that, fifteen patients were randomly assigned to receive either the conventional scalpel technique (Control Group, n = 7) or a diode laser-assisted technique (Laser Group, n = 8) for second-stage surgery of submerged dental implants placed at bone level. The local anesthetic amount required, and the total surgical time was determined just after surgery. Local pain, peri-implant mucosa status, and bleeding were assessed at the end of the surgery and after 7 and 15 days. Information on the need for postoperative pain medication on the first day and during the next two weeks was also gathered. The surgical time was significantly shorter in the Laser Group (P = 0.001) and only the Control Group presented bleeding at the end of surgery and on the seventh day (P = <0.001, P = 0.026). The other evaluations did not show differences between the groups. Within the limitations of the present pilot study and in comparison to clinical outcomes of the conventional scalpel

technique, the use of a high-power diode laser seems to be slightly advantageous for the second-stage implant surgery.

Keywords: Dental implants; Lasers; Oral surgery.

Resumen

El presente estudio tuvo como objetivo comparar la técnica convencional de bisturí y el uso de un láser de diodo de alta potencia en la segunda fase quirúrgica de implantes. Un total de quince pacientes fueron asignados aleatoriamente para recibir la técnica convencional de bisturí (Grupo de Control, n = 7) o una técnica asistida por láser de diodo (Grupo Láser, n = 8) en la segunda fase de la cirugía de implantes dentales sumergidos a nivel del hueso. Inmediatamente después de la cirugía, se registró la cantidad de anestesia local requerida y el tiempo quirúrgico total. Además, el dolor local, el estado de la mucosa periimplantaria y el sangrado se evaluaron al final de la cirugía y después de 7 y 15 días. Se obtuvo información sobre la necesidad de analgésicos postoperatorios el primer día y durante las dos semanas siguientes a la cirurgía. El tiempo quirúrgico fue significativamente más corto en el Grupo Láser (P = 0.001), y solo el Grupo de Control presentó sangrado al final de la cirugía (P < 0.001) y al séptimo día (P = 0.026). No hubo diferencia entre los grupos con respecto a los otros aspectos evaluados. Dentro de las limitaciones del presente estudio piloto, el uso del láser de diodo de alta potencia parece ser relativamente más ventajoso para la segunda fase de la cirugía de implantes en comparación con la técnica de bisturí convencional.

Palabras clave: Implantes dentales; Láseres; Cirugía oral.

1. Introduction

Edentulism is a common clinical entity considered as an expected part of aging (Bajaj et al., 2020). Dental implants, a titanium surgical fixture with a root form and placed at the original position of natural teeth (Tunc et al., 2019), have been advocated in recent decades as an excellent option to treat tooth loss (*Ibidem*, 2020), changing Dentistry (Fornaini et al., 2015). Following this trend, a large part of modern researches is based on novel alternatives and techniques to perform less aggressive oral surgical procedures (*Ibidem*, 2015).

High-power lasers (HPLs) were introduced in Dentistry in the mid-1970s and the use in oral surgery has been consecrated over time (Arnabat-Domínguez et al., 2010) thanks mainly to its ablation effect on soft tissues (Matys & Dominiak, 2016). Other utilizations include hard tissue surgery and assistance in orthodontic and prosthodontic procedures (Świder & Marzena,

2019); however, there has still been a lack of complete evidence regarding some aspects, proprieties, and applications of HPLs (*Ibidem*, 2010).

HPLs can reduce intraoperative bleeding and the need for anesthetic drugs, vasoconstrictor agents (Al-Delayme, 2019), and sutures (Arnabat-Domínguez et al., 2010). Furthermore, HPLs have antiseptic properties related to the avoidance of postoperative secondary infections and a bio-modulating potential for healing improvement (*Ibid*, 2019; Fornaini et al., 2015). Several studies have also reported that HPL is able to reduce pain during surgeries and provides better coagulation and wound healing and slighter swelling, edema, and scarring (Ibid, 2019).

With regards to Implantology, these laser devices are used in different procedures such as implant placement, second-stage surgery, peri-implant tissue management, and peri-implantitis treatment (El-Kholey, 2014; Kaur et al., 2018); however, there is not enough evidence-based information to confirm definitively their advantages over conventional techniques. Taking into account the intense debate on the different HPL systems adopted (Arnabat-Domínguez et al., 2010) and the lack of comprehensive information about the peri-implant tissues and patients' responses to HPLs, this pilot clinical trial aims to assess whether the use of a diode laser presents better outcomes than the conventional scalpel technique in second-stage implant surgery.

2. Methodology

Study design, ethical issues, and patient recruitment

A randomized clinical trial was conducted in a Brazilian private office (São Paulo, Brazil). Research Ethics Committees of the University of Santo Amaro (#3.399.540) had approved the study before any clinical procedure and written informed consent was obtained from all patients.

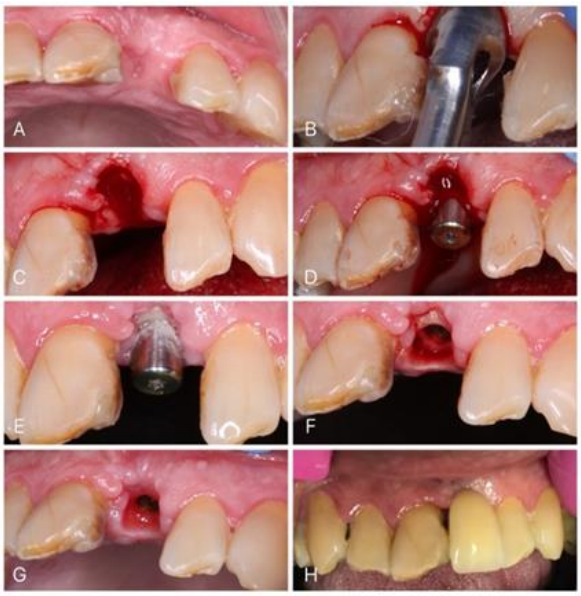
Individuals aged 18 or older and requiring a second-stage implant surgery (complete implant coverage) for a single tooth replacement were considered eligible for inclusion in the study. The following exclusion criteria were also considered: systemic diseases or medications known to alter healing processes and continuous use of analgesic and/or anti-inflammatory medications.

Study groups, clinical protocols, and procedures

Fifteen patients were randomly assigned to receive either the conventional scalpel technique (Control Group, n = 7) or an HPL-assisted technique (Laser Group, n = 8) for second-stage surgery of submerged dental implants, i.e., the installation of a healing abutment. For that, considering blocks with 4 individuals, randomization was performed using a computer-generated table and the treatment group for each patient was allocated into a numbered, opaque, sealed envelope that was opened just before surgery. The primary surgical protocol consisted of intraoral antisepsis with aqueous-based 0.12% chlorhexidine and local anesthesia with 2% lidocaine and 1:200,000 epinephrine (Xylestesin 2%™, Cristalia, Brazil). Besides, in patients from the Control Group was used circular scalpels (dimensions according to features of the implants) and in those from the Laser Group a high-power diode laser (Thera Lase Surgery™, DMC Ltda, Brazil) at 808 nm wavelength (continuous wave mode, optical fiber 400 μm, output power 1.5 W). A single operator carried out all the surgeries.

Figures 1 shows the clinical steps (from the initial aspect at the beginning of the second-stage implant surgery to the appointment for installation of the implant-retained crown) of a patient from the Control Group and Figure 2 of a patient from the Laser Group.

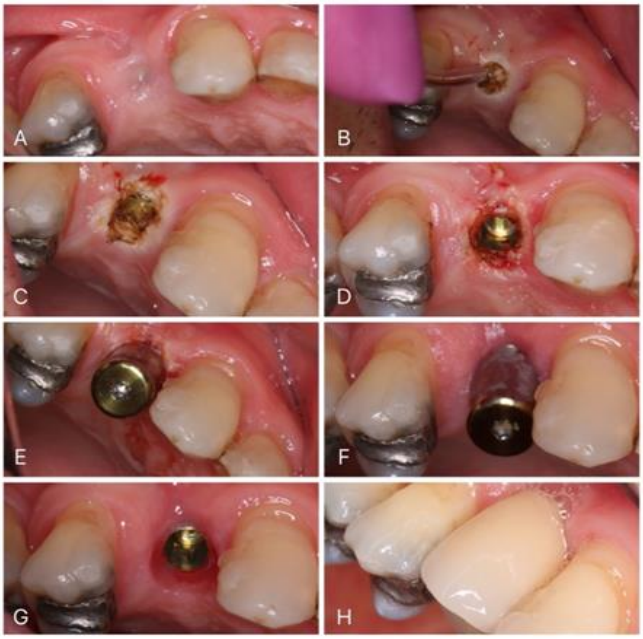
Figure 1. Example of clinical evaluation in a patient from the Control Group.



(A) Initial clinical aspect. (B) The trans-operatory procedures with the use of a circular scalpel. (C, D) Immediate post-operatory aspect and installation of a healing abutment. (E, F) 7 days after surgery. (G) 15 days after surgery. (H) Final rehabilitation.

Source: Authors.

Figure 2. Example of clinical evaluation in a patient from the Laser Group.



(A) Initial clinical aspect. (B) The trans-operatory procedures with the use of HPL. (C, D) Immediate post-operatory aspect. (E) Immediate installation of a healing abutment. (F) 7 days after surgery. (G) 15 days after surgery. (H) Final rehabilitation.

Source: Authors.

Evaluation of postsurgical outcomes

The local anesthetic amount required in each surgery was calculated based on the remaining solution within the cartridge and the total surgical time was determined in minutes by a digital timer.

A visual analog scale (VAS) composed of a horizontal line presenting values from 0 (no pain) to 10 (the worst pain imaginable) was used to asses pain arising from the implant sites at the end of the surgery and after 7 and 15 days.

Taking into account the same study periods, the peri-implant mucosa status was defined as healthy or biofilm-induced mucositis. Likewise, if present, bleeding was considered.

Information on the need for postoperative pain medication on the first day and during the two subsequent weeks was also gathered. The same operator who performed the surgical procedures conducted all evaluations.

Data synthesis

The patients' demographic characteristics and the surgical outcomes were organized using the Excel™ software (Microsoft, USA) and then submitted to both descriptive and inferential statistical analyses by the Statistics Package for Social Sciences v21.0™ software (SPSS Inc., USA).

The Shapiro-Wilk test was used to check data distribution and the Mann-Whitney and Fisher's Exact test were applied to identify differences between groups, with a *P*-value < 0.05 indicating statistical significance.

3. Results

Sample

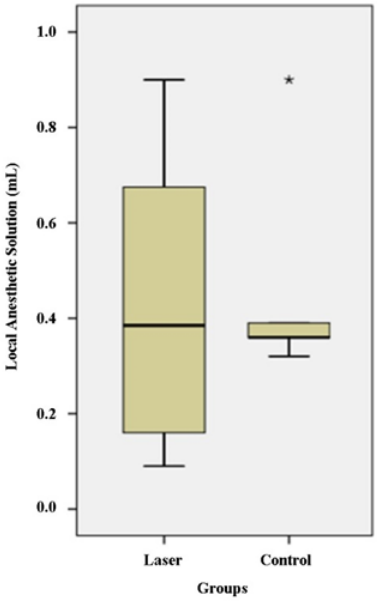
Fifteen patients were involved in the study, totaling 7 in the Control Group and 8 in the Laser Group.

The average age in the Control Group was 48.6 (±12.8) years (range 36-67) and in the Laser Group was 50 (±11.7) years (range 34-67). Furthermore, 5 patients were male and 2 females in the Control Group and 5 were female and 3 males in the Laser Group.

Postsurgical outcomes

Considering the amount of local anesthetic required, the averages in Control and Laser groups were 0.44 mL (±0.20) and 0.43 mL (±0.32), respectively (Figure 3). There is no statistically significant difference between them ($P = 0.770$, Mann-Whitney test).

Figure 3. Local anesthetic amount requirement for second-stage implant surgeries.

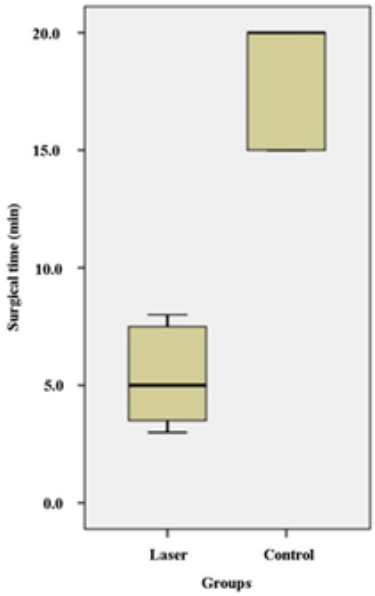


There was no statistically significant difference between groups (P = 0.770).

*Outlier value. **Source:** Authors.

On the other hand, the surgical time was shorter in the Laser Group (5.4 min, ±2.1) than in the Control Group (17.9 min, ±7.1), with a statistically significant difference (*P* = 0.001, Mann-Whitney test) (Figure 4).

Figure 4. Surgical time of the second-stage implant surgeries.



A statistically significant difference was obtained between groups (*P* = 0.001).

Source: Authors.

Bleeding was present only in the Control Group at the end of surgery and on the seventh day, with a statistically significant difference between groups by Fisher's Exact test (*P* = <0.001, *P* = 0.026). Detailed data are demonstrated in Table 1.

Table 1. Postsurgical bleeding.

Time	Bleeding	Groups		*P*
		Laser (n=8)	Control (n=7)	
Immediate	No	8 (100.0%)	0 (0%)	<0.001*
	Yes	0 (0.0%)	7 (100.0%)	
7th day	No	8 (100.0%)	3 (42.9%)	0.026*
	Yes	0 (0.0%)	4 (57.1%)	
15th day	No	8 (100.0%)	7 (100.0%)	-
	Yes	0 (0.0%)	0 (0.0%)	

*Statistically significant difference. **Source:** Authors.

No patient complained of pain immediately after surgery, as well as on the fifteenth day. Furthermore, no statistically significant difference was obtained between groups on the seventh day by the Mann-Whitney test (*P* = 0.407). Further information is presented in Table 2.

Table 2. Postsurgical pain.

Group	Pain	Time		
		Immediate	7th day	15th day
Laser (n=8)	Mean	0	0.13	0
	Standard Deviation	0	0.354	0
	Minimum	0	0	0
	Maximum	0	1	0
	Median	0	0	0
Control (n=7)	Mean	0	0.43	0
	Standard Deviation	0	0.787	0
	Minimum	0	0	0
	Maximum	0	2	0
	Median	0	0	0
P		-	0.407	-

There was no statistically significant difference between groups. **Source:** Authors.

With regards to peri-implant mucosa status, all cases had healthy peri-implant mucosa both immediately after surgery and on the fifteenth day; however, only one patient of the Control Group presented mucositis on the seventh day, data without statistically significant

difference between groups by Fisher's Exact test (*P* = 0.467). Detailed data are shown in Table 3.

Table 3. Peri-implant mucosa status postsurgical.

		Group		
Time	**Status**	**Laser (n=8)**	**Control (n=7)**	***P***
Immediate	Healthy	8 (100.0%)	7 (100.0%)	-
	Mucositis (biofilm)	0 (0.0%)	0 (0.0%)	
7th day	Healthy	8 (100.0%)	6 (85.7%)	0.467
	Mucositis (biofilm)	0 (0.0%)	1 (14.3%)	
15th day	Healthy	8 (100.0%)	7 (100.0%)	-
	Mucositis (biofilm)	0 (0.0%)	0 (0.0%)	

There was no statistically significant difference between groups. **Source:** Authors.

Likewise, 2 patients of Control group and 1 of Laser Group reported pain medication use only on the first day after surgery, data without statistically significant difference by Fisher's Exact test (*P* = 0.446). Further information is presented in Table 4.

Table 4. Postsurgical pain medication.

		Group		
Time	**Medication**	**Laser (n=8)**	**Control (n=7)**	***P***
1st day	No	7 (87.5%)	5 (71.4%)	0.446
	Yes	1 (12.5%)	2 (28.6%)	
7th day	No	8 (100.0%)	7 (100.0%)	-
	Yes	0 (0.0%)	0 (0.0%)	
15th day	No	8 (100.0%)	7 (100.0%)	-
	Yes	0 (0.0%)	0 (0.0%)	

There was no statistically significant difference between groups. **Source**: Authors.

4. Discussion

The present study evaluated comparatively some clinical outcomes of an HPL and the conventional scalpel technique for second-stage implant surgery. Despite the use of different techniques for it (e.g., scalpels, electrosurgery, and HPLs) (Tunc et al., 2019), HPLs have provided similar results when compared to the traditional ones with scalpels (Al-Delayme, 2019; Fornaini et al., 2015). Many studies on the use of HPL for oral soft tissue surgery are available but few assessed this matter especially.

Considering the surgical time, the current results are in line with data from the literature (*Ibid*, 2019; *Ibidem*, 2015). The HPL technique was considerably lesser time-consuming, which may reduce chair time and make the implant treatment better accepted by the patients.

Another advantage of the laser-assisted technique over the scalpel use was bleeding control, as reported by other studies (Al-Delayme, 2019; Kaur et al., 2018). According to beam types and power density, HPLs have been thought to be able to seal blood vessels up to a 0.5mm diameter and achieve instantaneous hemostasis (Anderson et al., 2013). At the end of the surgery and after 7 days, the HPL was efficient in avoiding bleeding; however, on the fifteenth day, there was no difference between both techniques. Although the local anesthetic solution used has epinephrine as a vasoconstrictor agent, which could have influenced on trans- and post-surgical bleeding, only the Control Group showed post-surgical bleeding. On the fifteenth day, the authors obviously expected no difference between both groups as within this period oral wounds have already healed.

With regard to the total local anesthetic amount, both techniques required almost the same mean volume. It has been advocated that in surgeries with HPLs the need for local anesthetic is considerably lower or even absent (El-Kholey, 2014; Kaur et al., 2018; Matys & Dominiak, 2016). A plausible explanation for the current results would be the variability of implant sites involved in the study, with different local features (e.g., mucosa thickness and blood supply).

Patients of both groups reported the need for pain medication intake only on the first postoperative day, with no difference between them, and no patient complaint of pain just after surgery, evidently due to the local anesthetic effect. Similarly to bleeding, reports of pain were not expected on the fifteenth day as within this period all the inflammation signs and symptoms have already disappeared as well. Although the Control Group showed a higher mean pain score on the seventh day, there was no difference between groups. This result appears not to be in accordance with the literature, in which HPLs has been supposed to reduce post-operative pain and discomfort (Al-Delayme, 2019; Arnabat-Domínguez et al., 2010; Kaur et al., 2018; Matys & Dominiak, 2016). Furthermore, a patient of the Control Group presented mucositis induced by biofilm on the seventh day, probably due to poor hygiene in response to local pain.

The authors believe the sample size was not sufficiently powered to detect differences between the groups concerning pain, need for pain medication, and peri-implant mucosa status, since some authorities have reported that HPLs have antiseptic properties related to the avoidance of postoperative secondary infections and a bio-modulating potential for healing improvement (Al-Delayme, 2019; Fornaini et al., 2015).

Besides the high price and specific operator training (*Ibidem*, 2015), HPL techniques have been thought to have some possible clinical disadvantages such as the need for sufficient adjacent keratinized tissues around the implant (Kaur et al., 2018) and previous knowledge of the implant localization (El-Kholey, 2014), direct damages to the implant surface topography (Bajaj et al., 2020), and bone overheating (*Ibid*, 2019). Although the authors faced no technical difficulty during the laser-assisted procedures and noted no harmful effect within the study period, further trials are warranted to enhance insight into the benefits and adverse effects of the HPLs in second-stage implant surgery.

5. Conclusion

Within the limitations of the present pilot study and in comparison to clinical outcomes of the conventional scalpel technique, the use of a high-power diode laser seems to be slightly advantageous for second-stage implant surgery.

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