

Research Article

Efficacy of power strips as an alternate pain relief method in dental extractions: a clinical trial

Amanpreet Kaur¹, Ramandeep Singh Gambhir^{2*}, Randeep Singh Mann³, Jyotsna Goyal⁴,
Bikramjit Singh Gill¹, Sanjeet Gill⁴

¹Department of Public Health Dentistry, Gian Sagar Dental College and Hospital, Ramnagar, Rajpura, Punjab, India

²Department of Public Health Dentistry, Rayat and Bahra Dental College and Hospital, Sahauran, Mohali, Punjab, India

³Department of General Dentistry, Ranbaj Hospital, Mohali, Punjab, India

⁴Department of Periodontology, Gian Sagar Dental College and Hospital, Ramnagar, Rajpura, Punjab, India

Received: 06 May 2016

Accepted: 07 May 2016

*Correspondence:

Dr. Ramandeep Singh Gambhir,
E-mail: raman2g@yahoo.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Reducing post-interventional inflammation and pain in odontostomatological surgery procedures, such as tooth extractions, implants or oral biopsies is a relevant clinical goal. Therefore the present study was conducted to access the effect of PowerStrips on the patients with the post-operative pain associated with the extraction of tooth.

Methods: A randomized clinical trial was conducted among 88 subjects who were to undergo non-surgical extraction of their tooth a private clinic. PowerStrips patch was applied on the side of extraction after the procedure. Post-procedure pain was assessed on the same day after tooth extraction before application of PowerStrips and three days after application by means of a 10 cm visual analogue scale (VAS) (from 0: no pain to 10: extreme pain). The data obtain from the study subjects were statistically evaluated using Paired t-test.

Results: The mean difference in VAS score after application of PowerStrips on 1st and 3rd day was found to be 4.68 which was found to be statistically significant ($P < 0.05$). The mean difference was found to be 4.75 in males and 4.67 in females. The difference in both the genders was found to be statistically significant. About 9.1% participants felt the need for analgesics when enquired.

Conclusions: PowerStrips were found to have a potent analgesic action with virtually no systemic adverse effects. However, further clinical trials are needed before the effectiveness of this technology can be really judged.

Keywords: PowerStrips, Analgesia, Extraction, Diclofenac

INTRODUCTION

The pain that follows extraction of any tooth is an acute, short-lasting (2 hours to 3 days) pain that reaches its maximum intensity during the early (first 4 hours) post-extraction period.¹ Oral non-steroidal anti-inflammatory drugs (NSAIDs) are effective in relieving mild or moderate pain, and they are more likely to be used in ambulatory patients compared with their injectable

counterparts.² Transdermal patches have been developed in the recent past as innovative topical drug delivery systems offering the advantage of sustained drug delivery with reduced incidence of systemic adverse effects due to lower plasma concentrations.^{3,4}

PowerStripsTM are ultrathin U.S. FDA-listed Class 1 medical device uniquely designed to provide temporary relief of minor aches and pains. It is a patented fusion of

modern energy and ancient herbs.⁵ They deliver the energy to the parts of the body that need it. Although the strips are not meant to cure chronic pain, they do seem to help alleviate pain and offer a more natural alternative to some pain medications. This technology is being called as “waveform energy.”

PowerStrips are a proprietary blend of herbs such as; germanium, Korean red ginseng, and marine phytoplankton which work together to provide a natural and easy to use pain relief transdermal patch.⁶ Germanium harnesses the energy from the body heat, the sun, and the environment and redirects it towards the area(s) of the body to which the PowerStrip is applied. It also breaks the heat into parts, component that is most effective for pain relief. As this heat is absorbed into the body, the blood vessel dilator increasing the blood flow, warmth and nutrients to the area. This dilation, in combination with other complimentary biochemical and neurological processes, amplifies your pain relieving results. Marine phytoplankton is the harvesting process that allows for instant nutrient bioavailability. Korean red ginseng allows molecules to have a longer half-life, which helps create an environment that is conducive to the healthy appearance.⁶

PowerStrips consist of two primary layers (Figure 1). The first is a woven matrix that allows for free exchange of air. This layer serves both as the foundation for the second adhesive layer and as a vehicle for particles of germanium. These are designed as a topical patch that combines natural ingredients with an integrated technology that promotes a robust environment for pain relief when applied to skin.⁷ Till date no studies have been conducted on the efficacy of PowerStrips as a pain relief method in dental extractions. Therefore the present study was conducted to evaluate the efficacy of PowerStrips in controlling post extraction pain and related adverse effects if any.

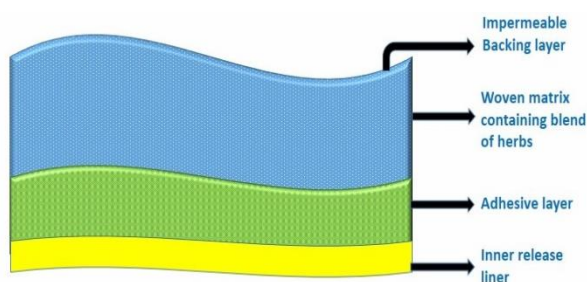


Figure 1: Cross-sectional view of the PowerStrip patch.

METHODS

The present study (randomized clinical trial) was conducted in a private dental clinic in Punjab, India after obtaining ethical clearance from the concerned authorities. The patients were fully informed about the

study undertaken and written informed consent was obtained. They were also assured that their unwillingness to participate in the study would not affect their treatment.

Study population and study sample

Study population consisted of subjects (patients) who were to undergo non-surgical extraction of their tooth at the clinic. A detailed medical and dental history of the clients is taken on a structured case-history sheet. A total of 88 patients were recruited in the study entirely on the basis of random sampling through random scheduling. Simple randomization was accomplished with a computer-generated sequence of numbers and sealed envelopes were used to allocate subjects into the study. Subjects undergoing treatment with any NSAIDs (Non-steroidal anti-inflammatory drugs) or any other analgesics or corticosteroids during the trial period and those with history of systemic diseases like bronchial asthma, epilepsy, and emotional psychosomatic disorders were excluded from the study. A sample size of 88 patients was calculated considering statistical power of 0.8 (β -1) and average effect of $d = 0.7$.

Intervention

In the preoperative visit, the patients were examined and investigated appropriately. Non-surgical extraction (closed method of extraction) was done of the particular tooth on the day of the appointment of the subjects. A time limit of 30 min were given for each patient; any procedure involving any other method other than the standard closed method of extraction or extension of the proposed duration of the procedure were excluded from the study. The standard post-extraction instructions were given, and the patients were given helpline numbers to contact in case of emergency.

Reasonably hair-free application site was selected on the side of extraction for the PowerStrip patch to be applied. The patch provides continuous and systemic release of herbal contents and is designed to remain at the site of application for 24 hours. One side was peeled off and the sticky side of the patch was applied to the skin. All the subjects were properly explained regarding the application of the PowerStrip patch before discharging. Subjects were advised to change the patch after every 24 hours and remove it thirty to sixty minutes before bathing. The patch delivers slow release of drug into the body over time, resulting in long-term effectiveness and added convenience.

Measurements

Visual analogue scale (VAS) was used to access the pain relief of the subjects.⁸ Patients were given a score number between 0 and 10, 0 representing no pain and 10 demonstrating the worst conceivable pain.⁹ Pain severity was assessed before extraction, first, second and third day

post-operatively. Adverse effects based on self-report and clinical manifestations were noticed. Subjects were also asked whether they required any other analgesics for pain relief. All the extractions were performed by the same operator, thus removing any operator-induced bias from the study.

Statistical analysis

The recorded data was transferred to a personal computer and statistical analysis was carried out using statistical package for social sciences (SPSS Inc., Chicago, IL, version 15.0 for Windows). The data obtained from the study subjects were statistically evaluated using paired t-test. Statistical significance was set at $p < 0.05$.

RESULTS

The mean age of study participants were 46.32 ± 12.53 years with 18.2% males and 81.8% females. On evaluating the variation in pain relief amongst the subjects, it was found that more than 90% of subjects reported of almost complete pain relief by the end of the third day. The mean score VAS score before application of PowerStrips after extraction was 5.45 ± 1.14 and mean VAS score after application of PowerStrips after three days was 0.77 ± 1.15 . This was found to be statistically significant ($p < 0.05$) (Table 1, Figure 2).

Table 2 depicts VAS score before and after application of power strips based on gender. The mean VAS score after application of PowerStrips was less in females as compared to males. The mean difference was found to be 4.75 in males and 4.67 in females. The difference in both

the genders was found to be statistically significant ($p < 0.05$).

Table 1: Depicts VAS score before and after application of power strips.

	Mean $\pm$ SD	Mean difference	T value	P-value
VAS score before	5.45 ± 1.14	4.68 ± 0.89	24.57	<0.001
VAS score after	0.77 ± 1.15			

Test used – Paired t-test; Statistically significant at $p > 0.05$.

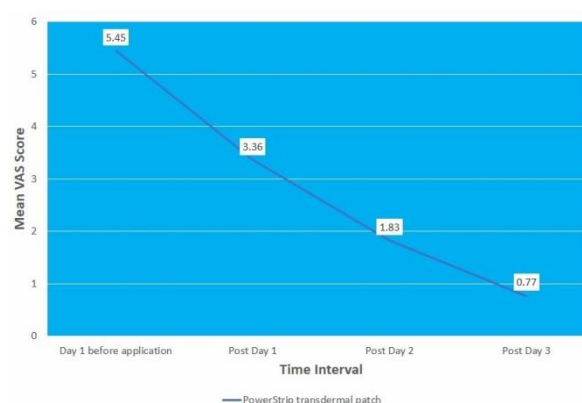


Figure 2: Difference in mean VAS score on the first day after extraction and after 3 days application of PowerStrip

Table 2: Depicts VAS score before and after application of power strips based on gender.

Gender		Mean $\pm$ SD	Mean difference	T value	P-value
Male	VAS score before	6.00 ± 1.15	4.75 ± 0.50	19.00	<0.001
	VAS score after	1.25 ± 1.50			
Female	VAS score before	5.33 ± 1.14	4.67 ± 0.97	20.41	<0.001
	VAS score after	0.67 ± 1.08			

Test used – Paired t-test; Statistically significant at $p > 0.05$.

When enquired about the need for analgesics for relief, 9.1% study resorted to some oral analgesics at the end of the third day. However, no adverse effects were reported from study subjects.

DISCUSSION

Managing post-extraction pain remains an arena for never ending research with better formulations and modalities continuously replacing older ones. Post-extraction pain has always been a nemesis for dental professionals and patients alike due to the considerable degree of inflammatory response involved.

Oral administration of NSAIDs are amongst the most common analgesic agents used to deliver post-operative dental pain. However, they carry a risk of first pass metabolism and significant amount of drug lost before it is systemically absorbed.¹⁰ These are also known to cause several adverse effects, which are dose dependent. Transdermal drug delivery is a painless, convenient, and potentially effective way to deliver regular doses of many medications.¹¹ Transdermal systems for NSAIDs and have been developed which have replaced oral and other traditional forms of drug administration.¹² These have also been routinely used as an analgesic following dental extractions.¹³

Although topical NSAIDs patches have been reported to provide effective analgesia in post-extraction cases, however according to a study report, 17.5% of patients using transdermal and topical NSAIDs reported systemic adverse effects, with one reported case of GI bleeding.^{14,15}

The present study utilized PowerStrips, a herbal formulation uniquely designed to provide temporary relief of minor aches and pains. Natural elements such as germanium, marine phytoplankton and red ginseng go into the making of PowerStrips to help provide optimum temporary relief of your common ailments.⁶ The PowerStrips are completely effortless to apply and the effects are nearly immediate while helping you minimize the pain in troubled areas of discomfort.

In the present study, the transdermal patch of PowerStrips used once daily was found to be as potent as transdermal patch of diclofenac for post extraction analgesia. Patients using PowerStrips patch reported a statistically and clinically significant reduction in pain scores after three days post-operatively, similar to those achieved with transdermal diclofenac patches.¹⁴ The mean VAS scores reduced considerably after three day application of PowerStrips patch in more than 90% of patients.

Sex-gender influences on pain and analgesia have become a hot topic and data regarding sex-gender differences in response to pharmacologic and non-pharmacologic pain treatments are still scanty. In the present study, the mean difference in VAS score before and after application of PowerStrips was more in case of males and females. This could be due to the influence of sex hormones in controlling pain post-operatively.¹⁶ However, this finding is contrary to some other study reports.¹⁷

In terms of safety, the patch was well tolerated and did not cause any type of local or systemic adverse effects. Reports of another study revealed that while using transdermal diclofenac patch for the attenuation of venous cannulation, there was an occurrence of localized erythematous rash or pruritis at the site of application of the transdermal patch.¹⁸ This finding is in contrast to the present study reports.

CONCLUSION

PowerStrips seem to be a promising analgesic modality for the management of mild to moderate pain following dental extractions. It is evident from the results that PowerStrips have a potent analgesic action with virtually no systemic adverse effects. This novel technology may have a role to play in management of post-traumatic pain. However, as the present study is the first of its kind to evaluate its effectiveness, longer clinical trials with a larger sample size need to be conducted among diverse populations before the real scope of the this technology can be clearly defined.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Levin L, Amit A, Ashkenazi M. Post-operative pain and use of analgesic agents following various dental procedures. *Am J Dent*. 2006;19:245-7.
2. Bocanegra M, Seijas A, González Yibirín M. Effectiveness and tolerability of once-daily nimesulide versus ibuprofen in pain management after surgical extraction of an impacted third molar: A 24-hour, double-blind, randomized, double-dummy, parallel-group study. *Curr Ther Res Clin Exp*. 2005;66:172-80.
3. Hadgraft J, Lane M. Passive Transdermal Drug Delivery Systems. Recent Considerations and Advances. *Am J Drug Deliv*. 2006;4:153-60.
4. Cranney A, O'Donnell S. Topical Diclofenac improved pain and physical function with no systemic side effects in primary osteoarthritis of the knee. *Evid Based Med*. 2005;10:81.
5. Power Strips -US FDA Class 1 Medical Device for Pain [monograph on the internet]. USA; 2015 [cited 2016 Jan 26]. Available from: www.workwithdaveandjoy.com/powerstrips-us-fda-class-1-medical-device-for-pain.
6. FGXpress Power Strips. A Unique Herbal Pain Relief Patch from FGXpress [monograph on the internet]. Montana, USA; 2016 [cited 2016 Jan 26]. Available from: www.basedonscience.com.
7. PowerStrips: A Double layer adhesive for pain relief [monograph on the internet]. Montana USA; 2016 [cited 2016 Jan 27]. Available from: www.spine-health.com/powerstrips.
8. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care Res (Hoboken)*. 2011;63:S240-52.
9. Faridaalae G, Rahmani SH, Mehryar H, Bina Shishavan S, Merghati SZ, Valizade Hasanloei MA, et al. Comparison of Intravenous Metoclopramide and Acetaminophen in Primary Headaches: a Randomized Controlled Trial. *Emerg (Tehran)*. 2015;3:70-4.
10. Naesdal J, Brown K. NSAID-associated adverse effects and acid control aids to prevent them: a review of current treatment options. *Drug Saf*. 2006;29:119-32.
11. Rehman K, Zulfakar MH. Recent advances in gel technologies for topical and transdermal drug delivery. *Drug Dev Ind Pharm*. 2014;40:433-40.

12. Grahame R. Transdermal non-steroidal anti-inflammatory agents. *Br J Clin Pract*. 1995;49:33-5.
13. Nasri-Heir C, Khan J, Heir GM. Topical medications as treatment of neuropathic orofacial pain. *Dent Clin North Am*. 2013;57:541-53.
14. Bhaskar H, Kapoor P, Ragini. Comparison of transdermal diclofenac patch with oral diclofenac as an analgesic modality following multiple premolar extractions in orthodontic patients: A cross over efficacy trial. *Contemp Clin Dent*. 2010;1:158-63.
15. McPherson ML, Cimino NM. Topical NSAID formulations. *Pain Med*. 2013;14:S35-9.
16. Campesi I, Fois M, Franconi F. Sex and gender aspects in anesthetics and pain medication. *Handb Exp Pharmacol*. 2012;214:265-78.
17. Averbuch M, Katzper M. Gender and the placebo analgesic effect in acute pain. *Clin Pharmacol Ther*. 2001;70:287-91.
18. Agarwal A, Dhiraaj S, Kumar A, Singhal V, Singh U. Evaluation of a Diclofenac transdermal patch for the attenuation of venous cannulation pain: A prospective, randomised, double-blind, placebo-controlled study. *Anaesthesia*. 2006;61:360-2.

Cite this article as: Kaur A, Gambhir RS, Mann RS, Goyal J, Gill BS, Gill S. Efficacy of power strips as an alternate pain relief method in dental extractions: a clinical trial. *Int J Community Med Public Health* 2016;3:1383-7.