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Original Article

Comparative cosmetic outcome of surgical incisions created by the PEAK Plasma Blade and a scalpel after cesarean section by Patient and Observer Assessment Scale (POSAS): A randomized double blind study

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ABSTRACT

Objective: To compare the cosmetic result of the PEAK Plasma Blade with traditional scalpel in patients who had primary cesarean delivery by using POSAS (Patient and Observer Assessment Scale).**Material and methods:** Forty women between 20 and 40 years, who were planning to have primary cesarean delivery, were randomized for skin incision with PEAK Plasma Blade (n:20) and with scalpel (n:20) were blinded to their group allocation. At six months, the cosmetic outcome of the cesarean scar was assessed using the POSAS. Subjective scar rating was performed using the patient component of the POSAS. Objective scar assessment was performed by an observer dermatologist blinded to the patient's group allocation.**Results:** The observer scores ($p = 0,003$), patient scores ($p = 0,001$) and the total scores ($p = 0,001$) of the POSAS scale were significantly lower in favor of the Peak Plasma Blade group with respect to the scalpel group.**Conclusion:** The PEAK Plasma Blade has superior cosmetic outcome compared to traditional scalpel skin incision at cesarean section.© 2018 Taiwan Association of Obstetrics & Gynecology. Publishing services by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Introduction

Every year cesarean sections (CS) are performed in millions of women world-wide, resulting in significant skin scarring. Due to the high frequency of CS, it is essential to determine the surgical incision technique rendering optimal cosmetic outcome of the incision scar [1]. The most widely used cutting instrument in surgery is the scalpel; however, scalpel incisions are prone to bleeding that obscures the operative field [2]. The PEAK Plasma Blade is an electro-surgical device that uses pulsed radio frequency to generate a plasma-mediated discharge along the exposed rim of an insulated blade. This plasma rim provides a cutting edge for precise tissue dissection with simultaneous homeostasis and lesser thermal damage by the blade staying near body temperature [3–5].

Patient and Observer Assessment Scale (POSAS) is a questionnaire that was developed to assess scar quality. It consists of two separate six-item scales (The Observer and The Patient Scales), both of which are scored on rating scale which are based on clinically relevant scar characteristics in 2004 [6,7]. The observer scores six items are vascularization, pigmentation, thickness, surface roughness, pliability, and surface area. The patient scores six items are pain, pruritus, color, thickness, relief and pliability [7]. All included items are scored on the same polytomous 10-point scale, in which a score of 1 is given when the scar characteristic is comparable to 'normal skin' and a score of 10 reflects the 'worst imaginable scar'. All items are summed to give a total scar score, and therefore, a higher score represents a poorer scar quality.

In the present study, we aimed to compare the cosmetic result of the PEAK Plasma Blade with traditional scalpel in patients who had primary cesarean delivery by using POSAS.

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Table 1

Difference between age and Patient and Observer Assessment Scale (POSAS) scores.

	Case group					Control group				p
	Mean ± s.d.	Med (Min–Max)			Mean ± s.d.	Med (Min–Max)				
Age	28,9 ± 4,8	28	21	–	40	29,1 ± 5,6	29	–	40	0,928
POSAS patient score	16 ± 6,2	16	6	–	28	24,5 ± 8,1	25	–	38	0,001
POSAS observer score	14,9 ± 6,2	15,5	6	–	28	24,4 ± 11,5	20,5	–	48	0,003
POSAS total score	30,9 ± 11,9	31,5	12	–	54	48,9 ± 18,6	43	–	85	0,001

Independent samples *t* test.Bold value represents $p < 0,05$.

Materials and methods

This randomized, double blind trial was performed at Bakirkoy Dr.Sadi Konuk Teaching and Research Hospital. The study was approved by the local institutional review board. From June 2013 until November 2013; women between 20 and 40 years, who were planning to have primary cesarean delivery at our institution, were invited to participate in this trial. Exclusion criteria included history of keloids, clinical signs of infection at the time of cesarean, pre-eclampsia, previous suprapubic incision scars and a medical disorder that could affect wound healing, such as known hypersensitivity to any of the suture materials used in the protocol, diabetes mellitus, and disorders requiring chronic corticosteroid use or immuno-suppression. The trial was explained and written informed consent was obtained.

Women undergoing cesarean section (CS) were randomized by the attending surgeon before skin incision, by drawing a sealed envelope containing the information regarding group allocation (i.e., case group: incision by plasma blade or control group: incision with scalpel). The envelopes were consecutively numbered according to the sequence of a computer generated randomization plan using one-to-one randomization. All cases received a single dose of intravenous cefazolin (1000 mg) as peri-operative single-shot antibiotic prophylaxis, when possible prior to skin incision. CS was performed by staff physicians or senior residents working at the delivery room. The CS was performed by a Pfannenstiel incision. Participants were blinded to their group allocation. In all participants the skin was closed using non-absorbable prolene 3-0; the wound was dressed with an abdominal pad and adhesive tape. The wound dressing was removed on post-operative day one. Subcuticular stitches were removed on post-operative day five to prevent wound disruption. Early post-operative ambulation was

used for thromboprophylaxis. Patients were hospitalized until the second post-operative day.

Patients were examined on the day of discharge from hospital and at the 7th post-operative day for the integrity of the wound closure, presence and location of any hematoma surrounding the wound. Participants were seen in follow-up after two months. At two months, the cosmetic outcome of the CS scar was assessed using the (POSAS) [6,7]. Subjective scar rating was performed using the patient component of the POSAS. Objective scar assessment was performed by an observer dermatologist blinded to the patient's group allocation. The study's primary outcome measures were patient and observer POSAS summary scores two months after CS.

Statistical analysis was performed with SPSS software (version 22.0; SPSS, Chicago, IL). The sample size was calculated to be 20 participants for each arm applying a 80% power, 5% error rate and 0,89 standard effect size. Continuous variables are summarized as median (range), and categorical data as percentages. Skewed distribution was tested via Kolmogorov Smirnov test. Paired *t* used at the comparison of the POSAS scores between the groups. *p* values of $<0,05$ were considered significant.

Results

A total of 40 participants, 20 in the plasma blade and 20 in the scalpel group were available for analysis. There was no wound hematoma, infection or wound dehiscence in both of the groups. There was no significant difference between age of the patients ($p > 0,05$) (Table 1).

Scar assessment at two months after CS revealed a significant difference between these two groups. The observer scores ($p = 0,003$), the patient scores ($p = 0,001$) and the total scores

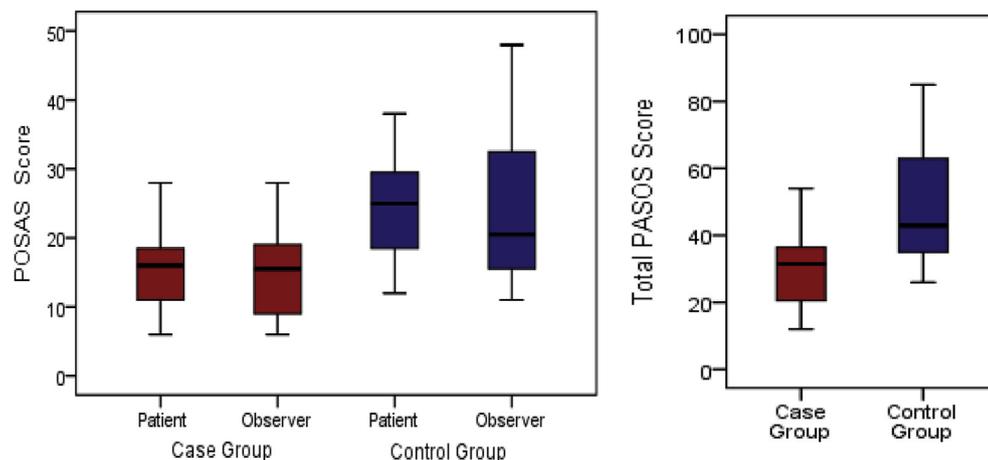


Fig. 1. Differences in observer, patient and total Patient and Observer Assessment Scale (POSAS) scores.

($p = 0,001$) of the POSAS scale were significantly lower in the Peak Plasma Blade group with respect to the scalpel group (Table 1 and Fig. 1).

Discussion

The PEAK Plasma Blade is a new electrosurgical device that uses pulsed radio-frequency to generate a plasma-mediated discharge along the exposed rim of an insulated blade, creating an effective cutting edge with less blade temperature than the electro-cautery. Shang et al. compared the effectiveness of the plasma blade with the scalpel and the conventional electro-cautery in full thickness skin incisions at dorsum of the pigs. They found that histologic scoring for injury and wound strength was equivalent between the Plasma Blade and scalpel incisions at 6th week. They also demonstrated that the healed Plasma Blade and scalpel incisions were approximately three times stronger, and scar cosmetic appearance was significantly better compared with electro-surgical incisions [5]. Ruidiaz et al. investigated thermal injury depth, inflammation, and scarring in abdominal skin of twenty patients undergoing abdominoplasty, by comparing the histology of incisions made with a standard “cold” scalpel blade, conventional electro-surgery, and the Plasma Blade. In their experimental model they demonstrated that Plasma Blade incisions had surface area reduced thermal injury depth, response, and scar width in healing skin compared with electro-surgical incisions. This study demonstrated the potential clinical advantage of Plasma Blade over conventional electro surgery on human cutaneous wound healing [8].

A poor incision scar is the only visible stigma after cesarean and it can cause considerable psychosocial distress. Different from the mentioned studies in favor of the Plasma Blade; our study compared the cosmetic outcome rather than the wound strength. Scalpel incisions are prone to bleeding that obscures the operative field and surgeons are generally use excessive electro-cauterization for the hemostasis of the sub-cuticular tissue. The electro-cautery uses continuous wave form radio-frequency. It is lack of surgical precision. Thermal injury to adjacent tissues such as nerves and blood vessels may cause delayed wound healing with poor cosmetic results. The thermal injury depends on the power settings used, duration and the intensity of the tissue. The extensive thermal injury may provoke a scar formation in all tissue layers of the

incision including the skin. Also thermal injury can spread to the skin in some patients causing poor cosmetic results. The Plasma Blade uses pulsed radio-frequency that generate a plasma-mediated discharge at the rim of insulated blade, that causes precise tissue dissection with simultaneous good hemostasis and less blade temperature than the electro-cautery. Actually the blade stays near body temperature because of the reduced duty cycle (fraction of time the energy is delivered) that allows for efficient cooling of the plasma blade [5]. This can be the explanation of the better cosmetic results obtained by the plasma blade.

Although it is a pilot study, the study group is enough for 80% statistical power. The double blind randomization and using both patient and observer POSAS strengthens the outcome of the study. Cosmetically, the low POSAS scores in both the observer and the patient scales supports using plasma blade in cesarean incision.

Conflict of interest

The authors have no conflicts of interest to declare.

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