

## Deep Hyperthermia Applicators: $\Sigma$ -60 or $\Sigma$ -Eye?

Daryoush Fatehi<sup>1\*</sup> and Gerard C van Rhoon<sup>2</sup>

<sup>1</sup>Department of Medical Physics, Shahrekord University of Medical Sciences, Shahrekord, Iran

<sup>2</sup>Department of Radiation Oncology, Unit Hyperthermia, Erasmus Medical Center, Daniel den Hoed Cancer Center, Rotterdam, The Netherlands

### Abstract

**Aim:** The goal of this study was functional evaluation of two deep hyperthermia (DHT) applicators to know whether we can replace  $\Sigma$ -60 with  $\Sigma$ -Eye (or vice versa).

**Methods:** Data of all 48 patients with locally advanced cervical cancer who were treated within both applicators were analyzed. No performance of the longitudinal SAR-steering (SAR: specific absorption rate) option of  $\Sigma$ -Eye was done; thus,  $\Sigma$ -Eye was used as an  $\Sigma$ -60 with a modified water-bolus and shape. Temperature and RF-power (RF: radio frequency) indices were analyzed. Additionally a subgroup-analysis was applied for subgroups, categorized for the reasons of switching between the two applicators.

**Results:** Analysis demonstrated a significant difference for power indices as applied to the two applicators; however, no difference was seen for temperature indices. The subgroup analyses revealed that when we applied  $\Sigma$ -Eye the power indices were mildly higher than those for the  $\Sigma$ -60. Contrarily, in majority of the patients applying  $\Sigma$ -Eye, number of off-switches and total switch-off time were lower than those for  $\Sigma$ -60. For the largest subgroup patients treated within the  $\Sigma$ -Eye, all temperature indices were slightly lower ( $\Delta T=0.2-0.5^{\circ}\text{C}$ ) than those for the  $\Sigma$ -60 ( $p<0.028$ ).

**Conclusion:** In case of severe patients discomfort for DHT applicator, or when we are not satisfactory for the achieved temperatures, one can freely switch between the  $\Sigma$ -60 and  $\Sigma$ -Eye or vice versa during a DHT treatment series without loss in quality of treatment.

**Keywords:** Hyperthermia; Applicator;  $\Sigma$ -60;  $\Sigma$ -Eye; Power; Temperature

### Introduction

In some western and European countries loco-regional deep hyperthermia (DHT) using RF-power is routinely applied with annular-phased-array applicators, i.e.,  $\Sigma$ -60 and  $\Sigma$ -Eye. Design of the  $\Sigma$ -Eye varies from the  $\Sigma$ -60 which its structure is different. An important advantage of the  $\Sigma$ -Eye applicator is that it can provide full 3D (three dimensional) control of the energy pattern. Furthermore, in  $\Sigma$ -60 applicator it has provided an energy steering in the longitudinal (Z) direction in addition to the energy steering as it has in the X- and Y-direction. In addition, the  $\Sigma$ -Eye applicator includes an improved water bolus design. This means that the length of the water bolus has been increased providing contact with nearly the whole skin of the body within the array. However, this advantageous decreases the focussing of energy. Moreover, thickness of the  $\Sigma$ -Eye water bolus, above the anterior patient's surface, is 1/2 to 1/3 of that of the  $\Sigma$ -60, which is expected to significantly rise comfortably of patient. In total, the elliptical shape of the  $\Sigma$ -Eye applicator is promoted to be more comfortable for patient [1]. Investigation on the new upgrading applicators and replacing them is interest of the HT departments around the world [2]. Cho et al. in a phase I/II study have reported that the  $\Sigma$ -Eye applicator heats the upper abdomen better than the  $\Sigma$ -60. Furthermore, they showed that in theory  $\Sigma$ -Eye provides  $1^{\circ}\text{C}$  temperature higher than  $\Sigma$ -60 [3]. Franckena et al. showed the existence of a thermal dose effect relationship for locally advanced cervical carcinoma (LACC) patients [4]. Thus, it would be of our interest to find out whether for the LACC patients switching between  $\Sigma$ -60 and  $\Sigma$ -Eye applicator, operated as a modified  $\Sigma$ -60 applicator; will result in an equal quality of DHT treatment. Purpose of the present study was to find the answer for this question.

### Methods

Radiotherapy (RT) was performed at different institutes in the

Netherlands. The patients received RT to the whole pelvis, conformal to the standard in the Netherlands, mostly 23-28 daily fractions of 1.8-2 Gy in 5 weeks in combination with a brachytherapy boost. For more details of the RT treatment see Van der Zee et al. [5].

DHT was performed using the BSD-2000 annular-phased-array system with the  $\Sigma$ -60 and the  $\Sigma$ -Eye applicators installed in Erasmus MC, Rotterdam (BSD Medical Corporation, Salt Lake City, Utah, USA) [6]. Selection of the  $\Sigma$ -60 or the  $\Sigma$ -Eye applicator was purely a matter of size of the patient, i.e. whether the patient would fit in the  $\Sigma$ -Eye under the condition that there was a distance of at least 2.5 cm between the dipole antennae and the body-surface. For a detailed description of patients, hyperthermia (HT), thermometry, data processing, variables, and statistical analysis see Fatehi et al. [7].

Of all LACC patients who have been treated with HT in addition to RT in the period of June 1999 to December 2005, in Rotterdam; 51 were treated within both the  $\Sigma$ -Eye and the  $\Sigma$ -60 applicator. In this retrospective study we used DHT data of 48 LACC patients (96 treatments, 2 treatments per patient). Three patients' data were not accessible. One of the treatments was performed within the  $\Sigma$ -60 and the other in the  $\Sigma$ -Eye. The cause that we switched from the  $\Sigma$ -60 to the  $\Sigma$ -Eye (or vice versa), was one of the following reasons: patient discomfort, out of ordering the applicator, unclearly for the patient that he/she would fit in the applicator, temperatures were not satisfactory,

**\*Corresponding author:** Daryoush Fatehi, Department of Medical Physics, Faculty of Medicine, Shahrekord University of Medical Sciences, Shahrekord, Iran, Tel:+983833335652; Fax: +983833334911; E-mail: [d.fatehi@gmail.com](mailto:d.fatehi@gmail.com)

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logistic problems, and unknown issues. Notice that in the present study, the  $\Sigma$ -Eye was used as a modified  $\Sigma$ -60 applicator. This means that there was no 3D-SAR (specific absorption rate) steering during the treatment. However, the SAR-steering was performed in lateral-lateral and posterior-anterior direction with the  $\Sigma$ -Eye in a similar matter as with the  $\Sigma$ -60. This means that the  $\Sigma$ -Eye, worked in the  $\Sigma$ -60 mode, was considered as a valid replacement for the  $\Sigma$ -60 applicator anticipating an equivalent quality of the HT treatment.

### Results

The results are summarized in Table 1. As Table 1 shows, in the first (and the largest) subgroup, "patients discomfort", all reported temperature indices were slightly (0.2-0.5°C) but significantly (p-values: 0.001-0.028) lower for the treatments delivered with the  $\Sigma$ -Eye. For the other five subgroups, temperature differences were small (and no statistically significant). In the analysis investigating the primarily treatment was performed by the  $\Sigma$ -60 and the other treatment by the  $\Sigma$ -Eye, we found an average vagina lumen T50 of 40.5°C for the  $\Sigma$ -60 vs. 40.4°C for the  $\Sigma$ -Eye (p=0.43). For the same group, but on the level of the individual patient, we noticed that the vagina lumen T50 for treatments applied by the  $\Sigma$ -60 were higher for 15 patients and equal or lower for 14 patients, in comparison to the vagina lumen T50 as obtained by the  $\Sigma$ -Eye. Furthermore, when the primarily treatment was performed by the  $\Sigma$ -Eye and the other treatment by the  $\Sigma$ -60, the average vagina lumen T50 was 40.5°C for both applicators (p=0.47).

As Table 1 reveals, the power related parameters, i.e., net power, net integrated power, and net integrated power per weight for the  $\Sigma$ -Eye applicator were 12-17% higher than those for the  $\Sigma$ -60; where the power indices for  $\Sigma$ -Eye were significantly higher than those for  $\Sigma$ -60 (p<0.002). Moreover, the number of power switch-off for  $\Sigma$ -Eye applicator was roughly equal to that of  $\Sigma$ -60. There was however a significant different between "each switched-off time" for the two applicators (p=0.04). Discomfort of the patient with the position in the applicator was the major reason to switch between the applicators. Malfunction of the applicator followed by doubt whether the patient would fit in the applicators were the next reasons to switch between the applicators. Only in 3 cases unsatisfactory temperatures as achieved by  $\Sigma$ -Eye was reason to switch to  $\Sigma$ -60.

### Discussion

The present study revealed no relevant difference between intraluminally measured temperatures for the LACC patients treated with either of the two applicators. Power analysis for the two applicators demonstrated that in all of the 48 patients, the power indices of the  $\Sigma$ -60 applicator were slightly lower than those for the  $\Sigma$ -Eye. Based on our knowledge on the characteristic of the  $\Sigma$ -Eye applicator these results are to be expected from the difference in RF-output efficiency between the  $\Sigma$ -Eye and  $\Sigma$ -60. In clinical treatment the difference in efficiency is also dependent on the phase's settings for the various antennas. Hence, the fact that in this study the power input indices for the  $\Sigma$ -Eye applicator are slightly higher than for the  $\Sigma$ -60 applicator is in good agreement with the differences in efficiency of the applicators.

Subgroup analyses performed for the whole patient group and the obtained results are also to be expected based on the anticipated better tolerance of the  $\Sigma$ -Eye due to its improved design. The  $\Sigma$ -Eye has less restriction on patient breathing, smaller water bolus thickness above the anterior surface of the patient, and the elliptical shape, which significantly improve patient comfort [2]. As in the present study the main reason to switch from the  $\Sigma$ -60 to the  $\Sigma$ -Eye applicator was the reported discomfort of patient during the previous treatment session it justifies subgroup analyses with regard to the reason of applicator exchange. Exchange due to complaints of discomfort occurred in roughly half of the patients. Overall, the subgroup analysis for the two applicators, demonstrates only relatively small differences in the measured temperatures. In addition, the intra-patient analyses are demonstrating identical results. When the primarily treatment was performed by the  $\Sigma$ -60 an average vagina lumen T50 of 40.5°C was achieved vs. 40.4°C for the  $\Sigma$ -Eye. When the applicator change was from  $\Sigma$ -Eye to  $\Sigma$  60 the average vaginal lumen T50 was 40.5°C for both applicators. Based on the individual patient T50's it follows that in more than half of the patients the vagina lumen T50 provided by  $\Sigma$ -60 was higher than those of  $\Sigma$ -Eye.

### Conclusion

The temperature and power analysis revealed that the differences in the quality of the HT are of the same order as those found between the subsequent treatments with the  $\Sigma$ -60 applicator only. Hence, we

Reason to switch the applicator type	Temperature and power index													
	Applicator type													
	Vagina lumen [°C]						RF-power related index							
	T <sub>90</sub>		T <sub>50</sub>		T <sub>20</sub>		Net power [W]		Net integrated power [kJ]		Net integrated power per weight [kJ/kg]		nr. of switched-off	
$\Sigma$ -60	$\Sigma$ -Eye	$\Sigma$ -60	$\Sigma$ -60	$\Sigma$ -60	$\Sigma$ -Eye	$\Sigma$ -Eye	$\Sigma$ -Eye	$\Sigma$ -Eye	$\Sigma$ -Eye	$\Sigma$ -60	$\Sigma$ -Eye	$\Sigma$ -60	$\Sigma$ -Eye	
Uncomforted patient during previous treatment session (n=23)	39.8* (0.9)	39.3 (0.8)	40.6* (0.9)	40.2 (0.9)	41.2* (0.9)	40.7 (1.0)	582* (145)	660 (118)	2577* (789)	3002 (706)	45.8* (13.7)	53.4 (13.4)	10.6 (5.5)	9.8 (5.5)
	p=0.004		p=0.028		p=0.005		p=0.037		p=0.027		p=0.025			
Applicator technical malfunction (n=12)	39.9 (1)	39.8 (1.1)	40.6 (1)	40.7 (1.2)	41.5 (1.8)	41.6 (2.1)	642 (177)	661 (165)	2683 (984)	2919 (919)	54.1 (20.9)	58.5 (17.5)	10.1 (5.6)	9 (6.3)
Doubtful if patient fits within the applicator (n=7)	39.3 (0.8)	39.5 (0.6)	40.1 (0.6)	40.5 (0.7)	40.9 (0.8)	41.1 (0.8)	596 (82)	696 (110)	2668* (533)	3300 (585)	50.1* (10.1)	62.4 (14.2)	13.1 (4.5)	12.1 (4.5)
							p=0.044		p=0.044					
Temperature not satisfactory (n=3)	39 (1)	39.3 (0.5)	40 (1.2)	40.5 (0.9)	40.7 (1)	41.3 (0.7)	558 (50)	714 (191)	2552 (333)	3278 (892)	47.3 (6.7)	61 (15.5)	9.3 (6.4)	11 (11.5)
Logistic (n=2)	40.5 (1.6)	39.8 (1.1)	41.3 (1.3)	40.8 (0.9)	41.7 (1.3)	41.3 (0.8)	670 (9)	808 (282)	3199 (68)	4006 (1512)	61.5 (0.7)	77 (29.7)	10.5 (4.9)	6.5 (3.5)
Unknown (n=1)	39.7	38.8	40.4	40.4	40.8	40.9	637	795	3316	3970	59	71	4	10

**Table 1:** Average values of temperature and power indices for the  $\Sigma$ -60 and the  $\Sigma$ -Eye applicators. Numbers in parentheses show 1 standard deviation (if exist). n: number of patients. \*: Statistical significant different from the value in the immediate next column.

conclude that when the patient has serious complaints on discomfort of one applicator type, technical or logistical unavailability of one applicator, provided  $\Sigma$ -Eye is used as a modified  $\Sigma$ -60 applicator; switching between  $\Sigma$ -60 and  $\Sigma$ -Eye applicator is a valid option to continue the HT treatment.

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