Simultaneous Integrated Boost–Intensity-Modulated Radiotherapy in Head and Neck Cancer

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Objectives/Hypothesis: To review toxicity and outcomes in patients with head and neck cancer treated with simultaneous integrated boost–intensity-modulated radiotherapy (SIB-IMRT).

Study Design: Review of experience with the SIB-IMRT technique.

Methods: Fifty patients were treated with the SIB-IMRT technique. Two possible schedules of radiation therapy (RT) were used: SIB 70 (70/60/54 in 33 fractions) and SIB 66 (66/60/54 in 33 fractions). Forty-one patients also received chemotherapy.

Results: All but two patients completed treatment as prescribed. No G4 acute toxicity has been reported in our series. We did not observe any G3 to G4 chronic toxicity, apart from one case of cutaneous necrosis. After a median follow-up of 23.3 months (range, 1–60 months), 41 patients (82%) were alive and negative for disease, and one patient (2%) was alive with distant metastases. Eight patients (16%) died, seven because of progressive disease and one for other causes.

Conclusions: SIB-IMRT is a highly effective and safe technique of RT in the treatment of head and neck cancer.

Key Words: Radiotherapy, head and neck, chemotherapy.

Level of Evidence: 4

INTRODUCTION

Radiation therapy (RT), alone or in combination with surgery and/or chemotherapy (CT), is commonly prescribed in the curative treatment of head and neck cancer. Although RT provides satisfactory results in terms of outcome, its use represents a major challenge due to the acute and late toxicities associated and the localization of the disease.1–3

Intensity-modulated radiotherapy (IMRT) is a RT technique that allows a sharp dose fall-off gradient, concave dose distributions, and narrower margins with a more conformal delivery of radiation to the planning target volume (PTV) if faced with conformal RT. In clinical practice, this results in a well-demonstrated sparing of organs at risk, reducing both acute and late toxicities,4–6 without any negative influence on the target volume coverage,7 and clinical results show control rates at least comparable with conventional RT.8,9

IMRT allows the simultaneous delivery of different dose prescriptions to different target volumes in the same treatment fraction; this technique is called simultaneous integrated boost (SIB).10 This approach reduces the overall treatment time and increases the fraction size to the boost volumes.

We reviewed our experience in the treatment of head and neck cancer with the simultaneous integrated boost–intensity-modulated radiotherapy (SIB-IMRT) technique. We focused on acute and late toxicity and reported locoregional control and overall survival.

MATERIALS AND METHODS

Between 2007 and 2010, 50 patients with head and neck cancer were treated in our department with the SIB-IMRT technique. Two possible schedules of RT were used, SIB 70 and SIB 66. In all patients, three target volumes were identified according to International Commission on Radiation Units and Measurements 62 guidelines.11 For nonoperated patients, the primary tumor and the clinically and/or radiologically involved nodes were treated with the higher dose of 70 Gy in 33 fractions, 5 days a week (according to Radiation Therapy Oncology Group [RTOG] protocol 0225). Similarly, in operated patients, 66 Gy in 33 fractions (derived from the RTOG 0022 study) were given to the tumor bed and involved nodes with extracapsular extension. Areas macroscopically not involved by the disease, but considered at high risk of subclinical disease, received 60 Gy in both schedules, whereas nodal regions with a low risk of being pathologically involved received 54 Gy, always in 33 fractions.

All patients underwent a virtual simulation with a planning CT (Big Bore Oncology; Philips, Andover, MA) or a positron-emission tomography/computed tomography (PET/CT)
Volumes were drawn on each CT slice; PET or magnetic resonance imaging (MRI) scans were coregistered in most cases for better definition of the targets. The three clinical target volumes (CTV) were expanded isotropically by 5 mm to obtain their respective PTVs. When expanding from CTV, PTV was automatically clipped to a margin of 3 mm inside the patient’s skin to allow the optimizer to neglect the first superficial millimeter corresponding to the build-up region. Organs at risk contoured for each patient included spinal cord, brainstem, cochleae, parotid glands, larynx, and mandible. The spinal cord and brainstem were isotropically expanded by 5 mm. Planning Organ at Risk Volume (PRV) had to be accounted for the effects of their possible displacement on the dose–volume histogram (DVH). The desired constraint for the contralateral parotid gland was a mean dose < 26 Gy, if this was not detrimental for PTV coverage. As constraints, for the mandible we used 75 Gy at 1 cm³ of the volume, and maximum dose to cord and cord PRV had to be < 44 and 50 Gy, respectively. Brainstem and brainstem PRV had a constraint of 54 Gy and 58 Gy, respectively; for the larynx we requested a mean dose < 50 Gy. For cochleae, we looked for a mean dose < 45 Gy. Contouring and plan optimizations were performed on the radiotherapy planning system Pinnacle version 9.2 (Philips Medical System, Bothell, WA) or on the XiO planning system, release 4.64 (CMS Inc., Maryland Heights, MO). IMRT step-and-shoot plans used an arrangement of seven to nine equally spaced 6-MV photon beams. Requirements on PTVs were to obtain a coverage of 95% of the prescribed dose to ≥ 95% of the volume. Hot spots with doses > 110% of the prescribed dose were considered acceptable if limited to a volume of ≤ 1%. All of our patients were asked to perform any dental interventions before the first day of treatment, reducing the need for such interventions during follow-up. Moreover, we asked for careful oral hygiene during treatment and during the months following treatment.

Treatment was delivered with an Elekta Precise (Elekta, Crawley, UK) linear accelerator equipped with the standard Elekta multileaf collimator (40 pairs of opposing leaves, 1-cm wide). Patient positioning verification was performed with a couple of orthogonal portal images to be matched with digital reconstructed radiographs obtained by simulation CT for the first three treatment fractions and then weekly. Setup errors ≥ 3 mm were corrected offline.

According to a specific quality assurance program used in our department, a plan is considered acceptable if > 90% of the examined points fulfills the constraint γ ≤ 1, with dose and distance limits of 3% and 3 mm, respectively.12

During treatment, patients were clinically evaluated weekly or according to their clinical conditions. Toxicities were recorded following Common Terminology Criteria for Adverse Events version 3.0.13 Maximum score registered is reported in this series. Xerostomia was assessed with the European Organization for Research and Treatment of Cancer Quality of Life—Head and Neck Cancer Module 35 questionnaire,14 before, during, and 1 year after the end of treatment. At 30 to 45 days after the end of the RT, patients visited the outpatient clinic with an ENT evaluation and a CT or a MRI. Follow-up was then conducted according to National Comprehensive Cancer Network guidelines.

**Statistical Analysis**

Survival analyses were carried out in relation to events/recurrences (local recurrences and distant metastases). Disease free survival (DFS), local recurrence free survival (LRFS), and overall survival (OS) were calculated. Time to events was measured from the last day of treatment to the date of first event occurrence. Overall survival was measured from the last day of RT to the date of either death or last follow-up. Patients who died before developing recurrent disease were considered censored at their dates of death. The crude probability of death or recurrence was estimated by using the Kaplan-Meier method. Univariate Cox regression models were used to evaluate the effect of each specific parameter. Statistical results were considered significant at a P value < .05. The statistical software package SAS version 9.1 (SAS Institute, Cary, NC) was used for statistical analyses.

**RESULTS**

The median age of patients was 52 years (range, 25–78 years), and more than half of the patients (80%) presented with stage III–IV disease; none had distant metastases at the time of diagnosis. Principal characteristics of the patients are listed in Table I. Fourteen patients underwent radical surgery, all other patients were referred to our institution for radical RT. All but 44 and 50 Gy, respectively. Brainstem and brainstem PRV had a constraint of 54 Gy and 58 Gy, respectively; for the larynx we requested a mean dose < 50 Gy. For cochleae, we looked for a mean dose < 45 Gy. Contouring and plan optimizations were performed on the radiotherapy planning system Pinnacle version 9.2 (Philips Medical System, Bothell, WA) or on the XiO planning system, release 4.64 (CMS Inc., Maryland Heights, MO). IMRT step-and-shoot plans used an arrangement of seven to nine equally spaced 6-MV photon beams. Requirements on PTVs were to obtain a coverage of 95% of the prescribed dose to ≥ 95% of the volume. Hot spots with doses > 110% of the prescribed dose were considered acceptable if limited to a volume of ≤ 1%. All of our patients were asked to perform any dental interventions before the first day of treatment, reducing the need for such interventions during follow-up. Moreover, we asked for careful oral hygiene during treatment and during the months following treatment.

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**Statistical Analysis**

Survival analyses were carried out in relation to events/recurrences (local recurrences and distant metastases). Disease
nine patients also received CT. Used schedules and compliance rates to CT are showed in Table II.

All except two patients completed the treatment as prescribed. Median overall treatment time, calculated from the first day of RT until the last delivered fraction, was 52.58 days (range, 40–80 days). Twenty patients (40%) never interrupted treatment; in all other cases, at least 1 day of suspension was necessary because of toxicity. The median for days of suspension was 7.58 days (range, 1–40 days).

A significant weight loss (>10% of the initial weight) was recorded during treatment in six cases (12%), and a minor decrease (>10% of the initial weight) was found in 10 other cases (20%). Gastrostomy for nutritional support was required in three cases. The most commonly reported acute toxicities were xerostomia and mucositis. No G4 acute toxicity had been reported in our series. Major observed acute toxicities are summarized in Table III.

Coverage of all PTVs was optimal, with a coverage of at least 95% of the prescribed dose to ≥95% of the volume. For organs at risk, in the contralateral parotid we obtained a mean dose of 34.1 Gy, with a value <26 Gy in seven patients (14%) and a V30 <50% in 34 patients (68%). For the mandible, we maintained a mean maximum dose of 72.1 Gy, with a dose <70 Gy in 10 patients (20%). The maximum dose to the spinal cord was maintained under a constraint of 44 Gy (mean maximum dose, 49.2 Gy). Average maximum doses to spinal cord, cord PRV, brainstem, and brainstem PRV were 43.4, 49.2, 50.6, and 55.4 Gy, respectively. The mean dose to the larynx and cochleae were 48.7 Gy and 34.2 Gy, respectively. Examples of dose distribution and DVH are given in Figures 1 and 2.

After a median follow-up of 23.3 months (range, 1–60 months), 41 patients (82%) were alive and still negative, and one patient (2%) was alive but with distant metastases at the last visit. Seven patients (14%) died because of progressive disease, and one patient (2%) died from other causes but was still negative for head and neck tumor at time of death. Four (8%) patients experienced a locoregional recurrence. Median occurrence time of locoregional relapse or persistence of disease was 104 days (range, 30–207 days). Distant metastases without locoregional recurrence occurred in five patients, with a median occurrence time of 243 days (range, 103–426 days). Treatments received by patients with locoregional relapse or distant metastases are listed

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**TABLE II.**

Chemotherapy Schedules and Compliance Rates.

<table>
<thead>
<tr>
<th>Intent</th>
<th>Schedule</th>
<th>No. of Patients</th>
<th>Cycles Prescribed</th>
<th>Cycles Received (No. of Patients)</th>
<th>Compliance Rate, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction</td>
<td>TPF</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CDDP-SFU</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Concomitant</td>
<td>CDDP, 35 mg/m²</td>
<td>27</td>
<td>5/6</td>
<td>1 (1)</td>
<td>59.3</td>
</tr>
<tr>
<td></td>
<td>CDDP, 100 mg/m²</td>
<td>10</td>
<td>2</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Cetuximab, 400/200 mg/m²</td>
<td>4</td>
<td>6</td>
<td>3 (2)</td>
<td>50</td>
</tr>
</tbody>
</table>

SFU = 5-fluorouracil; CDDP = cisplatin; TPF = docetaxel, cisplatin, 5-fluorouracil.

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**TABLE III.**

Acute Toxicities.

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>G0 (%)</th>
<th>G1 (%)</th>
<th>G2 (%)</th>
<th>G3 (%)</th>
<th>G4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mucositis</td>
<td>2 (4)</td>
<td>9 (18)</td>
<td>34 (68)</td>
<td>5 (10)</td>
<td>0</td>
</tr>
<tr>
<td>Skin toxicity</td>
<td>1 (2)</td>
<td>12 (24)</td>
<td>34 (68)</td>
<td>3 (6)</td>
<td>0</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>6 (12)</td>
<td>15 (30)</td>
<td>26 (52)</td>
<td>3 (6)</td>
<td>0</td>
</tr>
<tr>
<td>Dysphonia</td>
<td>48 (96)</td>
<td>0</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Xerostomia</td>
<td>24 (48)</td>
<td>13 (26)</td>
<td>11 (22)</td>
<td>2 (4)</td>
<td>0</td>
</tr>
</tbody>
</table>

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Fig. 1. Computed tomography slice showing an example of dose distributions in a patient primarily treated for squamous cell carcinoma of the supraglottic larynx. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]
in Table IV. Actuarial DFS was 80.8% ± 5.7% at 1 year and 78.1% ± 6.1% at 2 years. For LRFS, at 1 year and 2 years, 91.6% ± 4% of patients were free of disease in the head and neck region, because all local relapses in our series occurred in the first year (Fig. 3). Actuarial OS, considering death from all causes, was 89.5% ± 4.4% at 1 year and 82.4% ± 6.3% at 2 years (Fig. 4).

Use of CT, previous surgery for the head and neck cancer, stage, site, smoking, and drinking habits did not show a statistically significant association with acute or late toxicity at univariate analysis.

Patients were assessed for late toxicity, including side effects still present or begun after 6 months from the end of RT (Table V). We did not observe any G3–G4 chronic toxicity, apart from one case of cutaneous necrosis in the high-dose region. Although follow-up time is still short, none of our patients experienced osteonecrosis of the mandible or dental alterations requiring invasive procedures.

DISCUSSION

IMRT provides many advantages to the physician in the treatment of head and neck cancer, allowing higher doses to the target with optimal distribution and sparing of organs at risk. In particular, many experiences have been reported the ability of IMRT to spare parotid glands and to prevent or at least reduce xerostomia. Some phase II trials reported at the end of the 1990s that reducing the dose to parotid glands could improve the recovery of salivary flow.15–17 In 2011, the results of the phase III randomized Parotid-Sparing Intensity-Modulated Versus Conventional Radiotherapy in Head And Neck Cancer (PARSPORT) trial comparing IMRT with conventional RT were published, confirming a significant reduction of xerostomia in the IMRT arm both at 12 and 24 months.18 Another study, published in 2011 by Hey et al., showed that maintaining a dose of <26 Gy to at least one parotid gland can be enough for a return of the salivary flow to pre-RT values. The authors also reported that IMRT can obtain this result easier than conventional RT.19 Regarding our experience, very high doses were also given to the contralateral parotid. We obtained a mean value <26 Gy in only seven patients. Despite these results, it is interesting that none of our patient at 18 months reported G3–G4 late xerostomia, whereas 42% had some mild xerostomia (G1–G2). These results must be carefully evaluated as they are different from previously cited studies. Our

<table>
<thead>
<tr>
<th>Patient</th>
<th>LC Recurrence</th>
<th>DM</th>
<th>Primary Tumor</th>
<th>Surgery</th>
<th>RT</th>
<th>Induction CT</th>
<th>Concomitant CT</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>No</td>
<td>NP</td>
<td>No</td>
<td>70/60/54</td>
<td>3 TPF</td>
<td>3 weekly CDDP</td>
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<tr>
<td>2</td>
<td>Yes</td>
<td>No</td>
<td>OP</td>
<td>No</td>
<td>70/60/54</td>
<td>No</td>
<td>3 weekly cetuximab</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>No</td>
<td>HP</td>
<td>No</td>
<td>70/60/54</td>
<td>No</td>
<td>2 triweekly CDDP</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>No</td>
<td>OP</td>
<td>No</td>
<td>70/60/54</td>
<td>No</td>
<td>2 triweekly CDDP</td>
</tr>
<tr>
<td>5</td>
<td>No</td>
<td>Yes</td>
<td>NP</td>
<td>No</td>
<td>70/60/54</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>No</td>
<td>Yes</td>
<td>NP</td>
<td>No</td>
<td>70/60/54</td>
<td>No</td>
<td>No</td>
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<tr>
<td>7</td>
<td>No</td>
<td>Yes</td>
<td>NP</td>
<td>No</td>
<td>70/60/54</td>
<td>No</td>
<td>4 weekly CDDP</td>
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<tr>
<td>8</td>
<td>No</td>
<td>Yes</td>
<td>UP</td>
<td>No</td>
<td>70/60/54</td>
<td>2 TPF</td>
<td>5 weekly cetuximab</td>
</tr>
<tr>
<td>9</td>
<td>No</td>
<td>Yes</td>
<td>NP</td>
<td>No</td>
<td>70/60/54</td>
<td>3 TPF</td>
<td>5 weekly CDDP</td>
</tr>
</tbody>
</table>

CDDP = cisplatin; CT = chemotherapy; DM = distant metastases; HP = hypopharynx; LC = locoregional; NP = nasopharynx; OP = oropharynx; RT = radiation therapy; TPF = docetaxel, cisplatin, 5-fluorouracil; UP = unknown primary.
evaluation of xerostomia was done referring just to the symptoms reported by the patient, and we did not measure salivary flow with an objective method as other authors did. Amifostine is not routinely used in our Institution, and no patients in this series received it to better preserve salivary function. It is well known that this drug can protect salivary glands during RT in the head and neck region. However, we believe that dose sparing with IMRT can be more significant as has been reported.

With IMRT, a lower dose can be delivered to the mandible, allowing a decreased risk of osteoradionecrosis of the bone or other dental problems requiring extraction. Again, despite our dosimetric results, we did not register any case of radionecrosis or other dental complications. Our follow-up is too short to consider these results conclusive. However, we can underline the relevance of the specialist evaluation and the possible contribution of the reduction of severe xerostomia during treatment. All of these factors, in our opinion, must be carefully evaluated, being as important as reducing the dose given to the mandible to avoid late complications.

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Patients</th>
<th>Median Follow-up, mo</th>
<th>OS, %</th>
<th>LC, %</th>
<th>Time Point, yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kwong</td>
<td>50</td>
<td>25</td>
<td>92.1</td>
<td>95.7</td>
<td>2</td>
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<tr>
<td>Wolden</td>
<td>74</td>
<td>35</td>
<td>83</td>
<td>91 (local), 93 (regional)</td>
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</tr>
<tr>
<td>Chao</td>
<td>74</td>
<td>33</td>
<td>NA</td>
<td>87.7</td>
<td>4</td>
</tr>
<tr>
<td>Lauve</td>
<td>20</td>
<td>20</td>
<td>NA</td>
<td>76.3 (local), 66.7 (regional)</td>
<td>2</td>
</tr>
<tr>
<td>Studer</td>
<td>115</td>
<td>18</td>
<td>NA</td>
<td>77 (local), 87 (regional)</td>
<td>2</td>
</tr>
<tr>
<td>Schwartz</td>
<td>49</td>
<td>25</td>
<td>80</td>
<td>83</td>
<td>2</td>
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<tr>
<td>Montejo</td>
<td>43</td>
<td>37</td>
<td>73</td>
<td>82</td>
<td>2</td>
</tr>
<tr>
<td>Lee</td>
<td>71</td>
<td>46</td>
<td>81</td>
<td>82</td>
<td>3</td>
</tr>
<tr>
<td>de Arruda</td>
<td>50</td>
<td>18</td>
<td>98</td>
<td>88</td>
<td>2</td>
</tr>
<tr>
<td>Our series</td>
<td>50</td>
<td>23</td>
<td>82.4</td>
<td>91.6</td>
<td>2</td>
</tr>
</tbody>
</table>

A small number of patients (10%) experienced grade 3 acute mucositis in this series, despite the use of SIB. This phenomenon, suggesting a higher tolerance of normal tissues surrounding PTV, could be correlated with the large amount of mucosa that can be spared with IMRT and that compensate the higher dose received by a small volume, as other authors have previously reported.

In our opinion, several factors influence the dosimetric results we report in this study. First of all, the volumes treated are very different among patients in our series, reflecting the heterogeneity of diseases we reported. This also implies, in some cases, the impossibility of sparing some organs, such as the mandible or larynx, because of the proximity or the infiltration of the disease. For this reason, in some patients doses are higher than the normally used constraints, thereby increasing the average doses in the whole series. Sparing of the contralateral parotid was difficult, because in many patients disease (T stage or N stage) extended bilaterally, requiring high doses to be delivered to all gross disease. Furthermore, during the years of this study, there was a progressive improvement of technologies available in our institution, such as the use of PET-CT for simulation or the introduction of planning systems with new optimization and segmentation algorithms.

The disease distribution of primary tumors we report is quite unusual for a head and neck cancer series, with nasopharynx as the predominant site. The
explanation is quite simple. Patients treated by us with SIB-IMRT were those in which we expected a major advantage with this technique, exactly as patients with a primary tumor in the nasopharynx. During the study’s time period and for other sites, we continued to also treat our head and neck patients with conformal RT, especially in the earlier years. Another interesting observation on our series is the very high number of unknown primary sites in this series, diagnoses confirmed after PET/CT and ear, nose, and throat evaluation under general anesthesia. As for nasopharynx patients, this diagnosis from the beginning was an indication for SIB-IMRT.

There are not many published institutional studies in the literature of SIB-IMRT use in head and neck cancer. One of the largest and more interesting was published by Studer et al. in 2006.25 In this article, 115 patients were treated with three possible different SIB schedules: 5 to 6 Gy/week to 60 to 70 Gy, 5 to 2.2 Gy/week to 66 to 68.2 Gy, or 5 × 2.11 Gy/week to 69.6 Gy, with a good profile of tolerability and good results after a mean follow-up of 18 months.

The SIB technique allows shorter overall treatment time, mild hypofractionation, and possibly a dose escalation. This can be an advantage in terms of local control and survival, because boost volume is treated with a dose at least higher than the conventional dose.26 Furthermore, from a purely dosimetric point of view, some studies showed better dose distributions with SIB-IMRT than with conventional IMRT.10,27,28 This technique appears to be a radiobiologically effective RT strategy for head and neck cancer and also a new way to investigate RT acceleration.29 All of these advantages should theoretically translate to better local control and survival for patients. The results reported in our experience concerning LRFS, DFS, and OS are in accord with other similar reported experiences.25,26,30–36 (Table VI) and seem to support this hypothesis. Future randomized trials could give a stronger confirmation to this belief.

CONCLUSION
SIB-IMRT is a highly effective technique of RT in the treatment of head and neck cancer. It is safe, with a good profile of tolerability, and can be used with concomitant chemotherapy. Results in terms of local control and OS are at least equal to those obtained with conventional RT.

BIBLIOGRAPHY


