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Elekta Xoft®

Pierfrancesco Silli
Director Business Development Elekta Brachy Solutions

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LPTEBX241030

Elekta Xoft System

The Elekta Xoft Axxent Electronic Brachytherapy (eBx) System **delivers localized, high-dose radiation** using a 50 kV miniaturized x-ray source. Its **CE marked and FDA cleared**. It is currently utilized in three RT field modalities like IORT, HDR, Orthovoltage/Contact therapy.

- Increase patient access
- Cost effective solution
- Improve operational efficiency
- Mobile and portable

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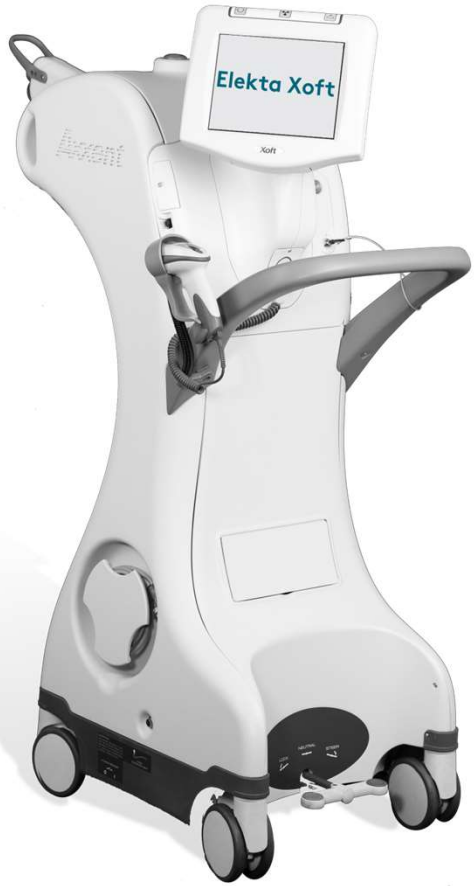
Elekta Xoft: One system. Multiple solutions.

A multiple indication platform with only three main components **x-ray source**, **controller** (in-built software) and **applicators**.



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Journey so far...

Decades of dedication to advancing cancer care—starting with breast IORT in 2007 and expanding targeted treatments for endometrial, skin, cervical cancers and beyond.

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More than 40,000 patients have been treated worldwide with the Xoft System

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165+ Installations worldwide

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Xoft now part of Elekta!

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Our mission

Everyone has access to cancer care

Contribute to a sustainable future

Keep looking forward

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Why eBx?

- Operates at 50kV, low photon beam energies
- Portable and ergonomic
- Versatile platform, 3 medical devices in 1
- Combined Dose Output
- Minimally Invasive Technology
- X-rays Tube fundamental component to dispose
- Primary standard calibration

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Elekta Brachytherapy

All the essentials of brachytherapy in one place, so you can focus on patient care.

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Elekta Xoft empowers institutions to expand cancer care **to more patients** by enhancing **operational efficiency** with **mobile and minimally shielded** technology that's also **cost-effective.**

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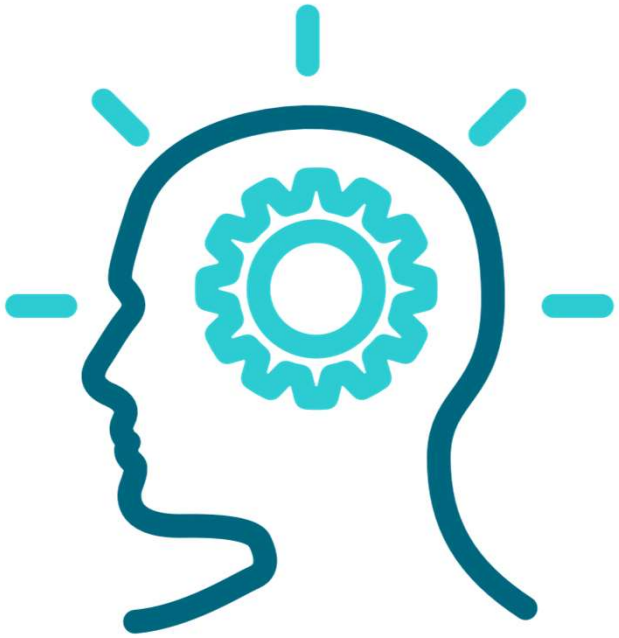
Hope for everyone
dealing with cancer.

Disclaimer:

Concepts are still in development and may be subject to change.

What are we working on?

1. ACCESS 2025 : Expand in geographies to better support developing countries
2. Improve miniaturized source life to increase productivity and cost effectiveness
3. Expand balloon volume range
4. Continuous radiobiological effectiveness investigation



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Xoft Breast (IORT) Solution

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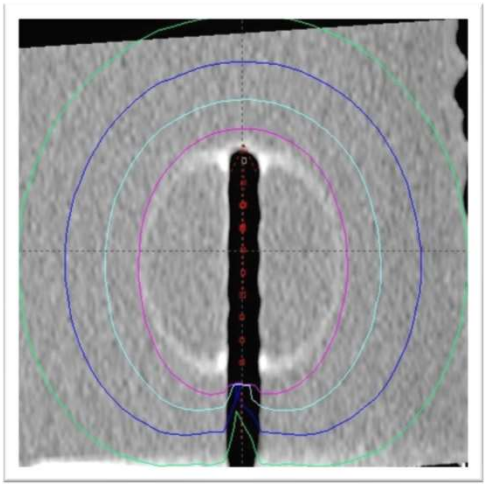
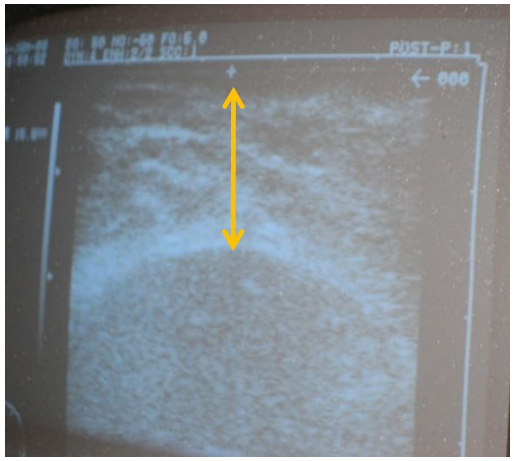
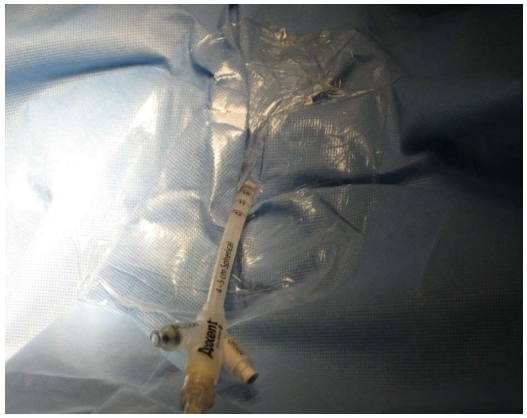
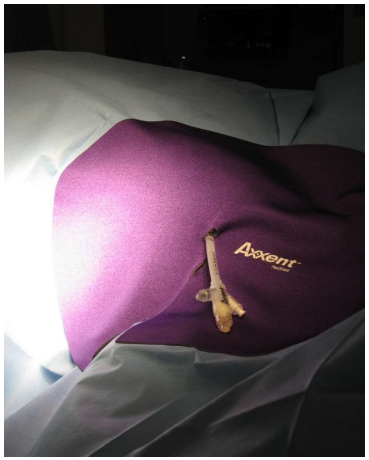
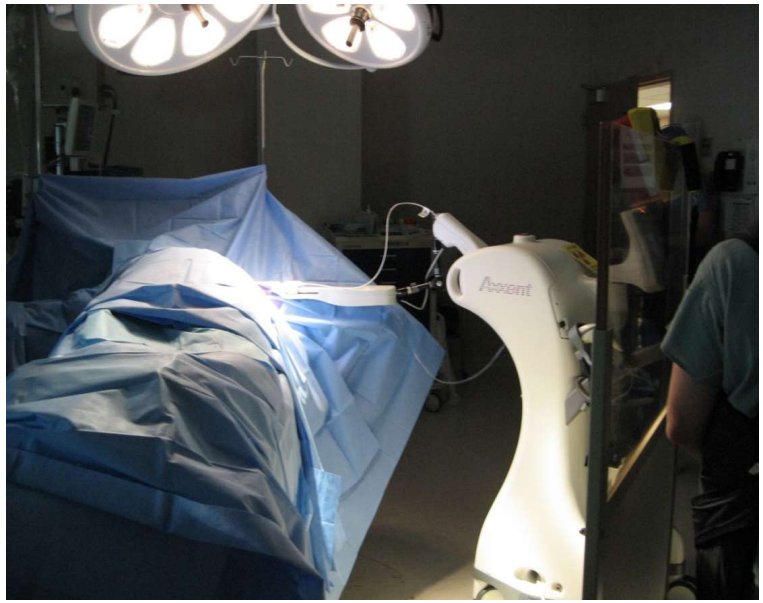
IORT, Breast, single fraction monotherapy or boost











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Xoft Balloon Applicator (IORT)

- Several Sizes
  - 3-4 cm
  - 4-5 cm
  - 5-6 cm
- Disposable
- Flexible
- Dwell Positions
- CE/FDA Whole Body

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Breast: Clinical Data and Patient Profile

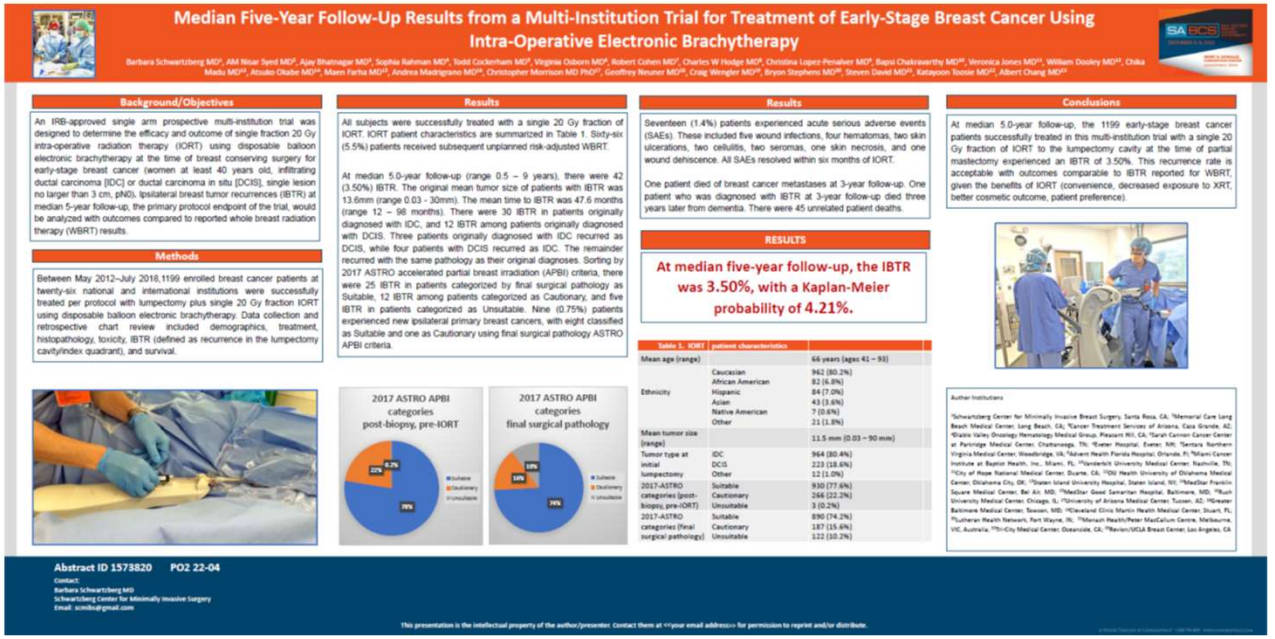
Clinical Data

Reference	Summary	Findings
TARGIT-A Trial *August 2020*	▪ Results concluded that IORT is an effective alternative to EBRT, with comparable long-term efficacy for cancer control and lower non-breast cancer mortality	▪ 2,298 patients ▪ 5-year complete follow up ▪ Pre pathology: – LR 2.11% IORT vs 0.95% WBRT
Annals of Surg Onc *July 2018*	▪ Results concluded that the recurrence rates observed in this trial were comparable to those of the prospective randomized TARGIT-A and ELIOT trials. The low complication rates previously reported by our group as well as the low recurrence rates reported in this study support the cautious use and continued study of X-ray IORT in women with low-risk breast cancer.	▪ 1,000 distinct breast cancers in 984 patients (16 bilateral) were treated with breast conserving surgery and X-ray IORT from June 2010 to August 2017 ▪ 28 ipsilateral local recurrences, 10 DCIS and 18 invasive ▪ No breast cancer related deaths and 14 non-breast cancer deaths with a median follow-up of 36 months, Kaplan-Meier analysis projects 3.9% of patients will recur locally at 4 years.

Patient Profile

▪ Radiation oncologists are most likely to recommend female patients with the following characteristics for single-fraction therapy:

Selected Factors	ASTRO Guidelines 2016
Age	>50 years
T-size	< 2cm
T-stage	Tis or T-1
Histology	Invasive/DCIS
Margins	Negative by >2mm
ER	Positive



Median Five-Year Follow-Up Results from a Multi-Institution Trial for Treatment of Early-Stage Breast Cancer Using Intra-Operative Electronic Brachytherapy

Barbara Schwartzberg MD[1], AM Nisar Syed MD[2], Ajay Bhatnagar MD[3], Sophia Rahman MD[4], Todd Cuckerham MD[5], Virginia Osborn MD[6], Robert Cohen MD[7], Charles W Hodge MD[8], Christina Lopez-Penalver MD[9], Bapsi Chakravarthy MD[10], Veronica Jones MD[11], William Dooley MD[12], Chika Madu MD[13], Atsuko Okabe MD[14], Maen Farha MD[15], Andrea Madrigrano MD[16], Christopher Morrison MD PhD[17], Geoffrey Neuner MD[18], Craig Wengler MD[19], Bryon Stephens MD[20], Steven David MD[21], Katayoon Toosie MD[22], Albert Chang MD[23]

Background/Objectives

An IRB-approved single arm prospective multi-institution trial was designed to determine the efficacy and outcome of single fraction 20 Gy intra-operative radiation therapy (IORT) using disposable balloon electronic brachytherapy at the time of breast conserving surgery for early-stage breast cancer (women at least 40 years old, infiltrating ductal carcinoma [IDC] or ductal carcinoma in situ [DCIS], single lesion no larger than 3 cm, pN0), lpsilateral breast tumor recurrences (IBTR) at median 5-year follow-up, the primary protocol endpoint of the trial, would be analyzed with outcomes compared to reported whole breast radiation therapy (WBRT) results.

Methods

Between May 2012–July 2018,1199 enrolled breast cancer patients at twenty-six national and international institutions were successfully treated per protocol with lumpectomy plus single 20 Gy fraction IORT using disposable balloon electronic brachytherapy. Data collection and retrospective chart review included demographics, treatment, histopathology, toxicity, IBTR (defined as recurrence in the lumpectomy cavity/index quadrant), and survival.

Results

All subjects were successfully treated with a single 20 Gy fraction of IORT. IORT patient characteristics are summarized in Table 1. Sixty-six (5.5%) patients received subsequent unplanned risk-adjusted WBRT.

At median 5.0-year follow-up (range 0.5 – 9 years), there were 42 (3.50%) IBTR. The original mean tumor size of patients with IBTR was 13.6mm (range 0.03 - 30mm). The mean time to IBTR was 47.6 months (range 12 – 98 months). There were 30 IBTR in patients originally diagnosed with IDC, and 12 IBTR among patients originally diagnosed with DCIS. Three patients originally diagnosed with IDC recurred as DCIS, while four patients with DCIS recurred as IDC. The remainder recurred with the same pathology as their original diagnoses. Sorting by 2017 ASTRO accelerated partial breast irradiation (APBI) criteria, there were 25 IBTR in patients categorized by final surgical pathology as Suitable, 12 IBTR among patients categorized as Cautionary, and five IBTR in patients categorized as Unsuitable. Nine (0.75%) patients experienced new ipsilateral primary breast cancers, with eight classified as Suitable and one as Cautionary using final surgical pathology ASTRO APBI criteria.

Results

Seventeen (1.4%) patients experienced acute serious adverse events (SAEs). These included five wound infections, four hematomas, two skin ulcerations, two cellulitis, two seromas, one skin necrosis, and one wound dehiscence. All SAEs resolved within six months of IORT.

One patient died of breast cancer metastases at 3-year follow-up. One patient who was diagnosed with IBTR at 3-year follow-up died three years later from dementia. There were 45 unrelated patient deaths.

RESULTS

At median five-year follow-up, the IBTR was 3.50%, with a Kaplan-Meier probability of 4.21%.

Table 1. IORT patient characteristics		
Mean age (range)		66 years (ages 41 – 93)
Ethnicity	Caucasian	962 (80.2%)
	African American	82 (6.8%)
	Hispanic	84 (7.0%)
	Asian	43 (3.6%)
	Native American	7 (0.6%)
	Other	21 (1.8%)
Mean tumor size (range)		11.5 mm (0.03 – 90 mm)
Tumor type at initial lumpectomy	IDC	964 (80.4%)
	DCIS	223 (18.6%)
	Other	12 (1.0%)
2017-ASTRO categories (post-biopsy, pre-IORT)	Suitable	930 (77.6%)
	Cautionary	246 (22.2%)
	Unsuitable	3 (0.2%)
2017-ASTRO categories (final surgical pathology)	Suitable	890 (74.2%)
	Cautionary	187 (15.6%)
	Unsuitable	122 (10.2%)

Conclusions

At median 5.0-year follow-up, the 1199 early-stage breast cancer patients successfully treated in this multi-institution trial with a single 20 Gy fraction of IORT to the lumpectomy cavity at the time of partial mastectomy experienced an IBTR of 3.50%. This recurrence rate is acceptable with outcomes comparable to IBTR reported for WBRT, given the benefits of IORT (convenience, decreased exposure to XRT, better cosmetic outcome, patient preference).

Abstract ID 1573820 PO2 22-04

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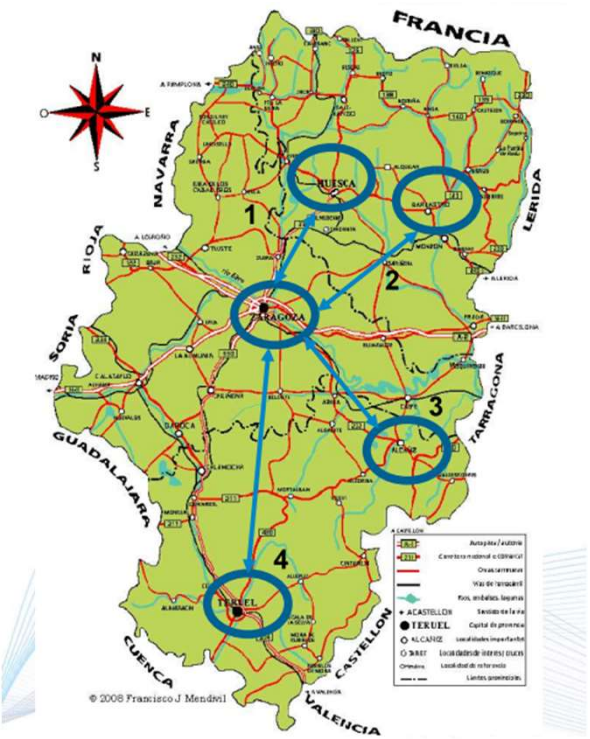
Mobile platform



1: Zaragoza – Huesca : **74 km**
2: Zaragoza – Barbastro : **131 km**
3: Zaragoza - Alcañiz : **105 km**
4: Zaragoza – Teruel : **171 km**

- Round trip within the day, travelling with a radiotherapy oncologist and a medical physicist from Zaragoza.
- Hospitals with own operating theatre and surgical team
- Machine travels from Zaragoza
- Patients are treated in their own city.

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Xoft Skin Solution

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Xoft Surface Applicator

- Several Sizes
  - 10, 20, 35, 50 mm
- 8 fractions <5min
- Integrated Filter
- ≤4cm size; ≤5mm depth
- Uniform Dose Distribution
- Other indications at MD choice

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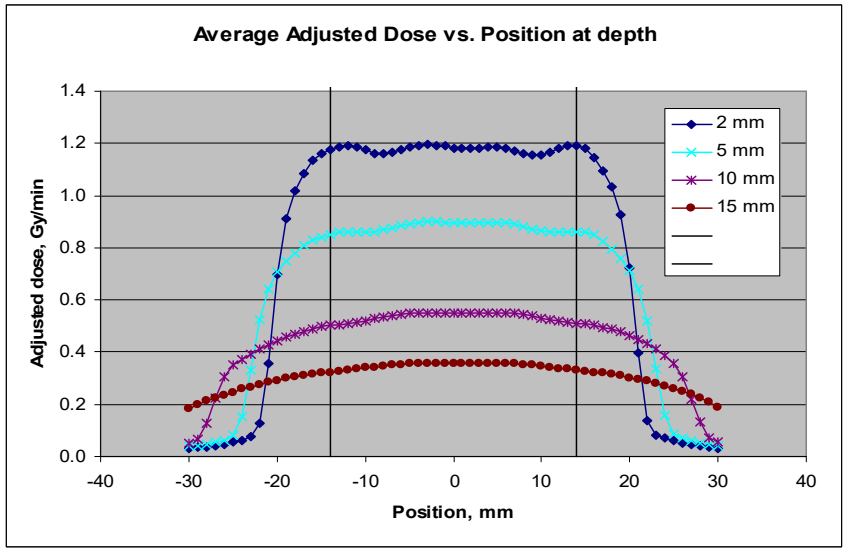
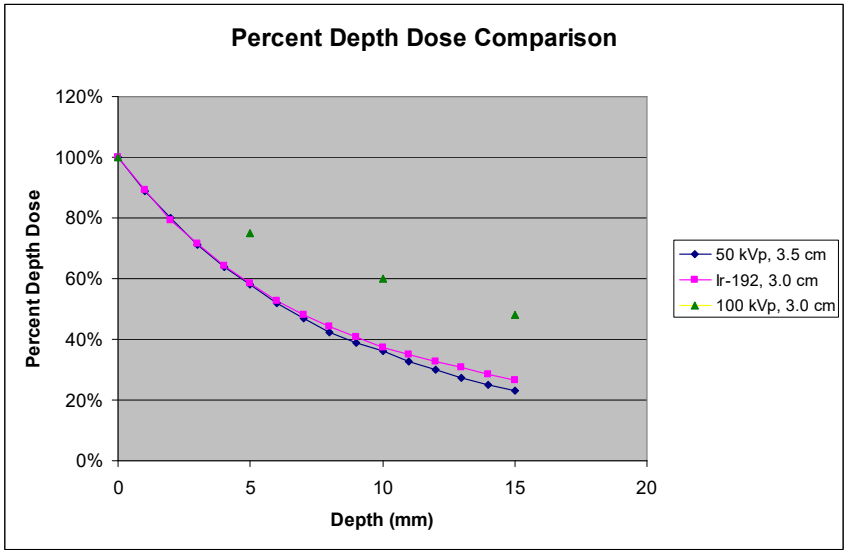
Dosimetry

- Flat dose in ~80% applicator diameter
- Similar to Valencia and more conformal than Leipzig





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Skin: Clinical data

Clinical Data		
Reference	**Summary**	**Findings**
Journal of Contemporary Brachytherapy *August 2017*	▪ Results show comparable recurrence rates for treatment of appropriately-selected NMSC using Xoft compared to Mohs surgery	▪ 416 lesions (208 eBx, 208 Mohs) ▪ 3.4 years mean follow-up ▪ <1% recurrence rate ▪ Cosmesis rated as "excellent" or "good" in 97.6% of EBT-treated lesions, and 95.7% of MMS-treated lesions
The Journal of Clinical and Aesthetic Dermatology *November 2016*	▪ Results show electronic brachytherapy is an effective, convenient, nonsurgical treatment option for patients with nonmelanoma skin cancer with few recurrences and excellent cosmetic results	▪ 1,822 lesions ▪ 4-16 months mean follow-up ▪ <1% recurrence rate

Long-term clinical outcomes of non-melanoma skin cancer patients treated with electronic brachytherapy

Stephen W. Doggett, MD, FACR[1], Mark Willoughby, MD[2], Kenneth A. Miller, MD[3], Erick Mafong, MD[2]
[1]Aegis Oncology, Newport Beach, CA, USA, [2]Dermatology and Laser Center of San Diego, San Diego, CA, USA, [3]Kenneth Miller Dermatology, Los Gatos, CA, USA

Conclusions: Electronic brachytherapy for the treatment of non-melanoma skin cancer is safe and effective, showing excellent long-term 98.9% local control through a median follow-up of 7.6 years (n = 183), with minimal long-term toxicities.

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Xoft GYN Solution

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Xoft Vaginal Applicator

- Several Sizes
  - Diameter 20 mm, length 102 mm
  - Diameter 25 mm, length 103 mm
  - Diameter 30 mm, length 106 mm
  - Diameter 35 mm, length 107 mm
- Adjustable clamp
- Base plate size 40 cm x 50 cm

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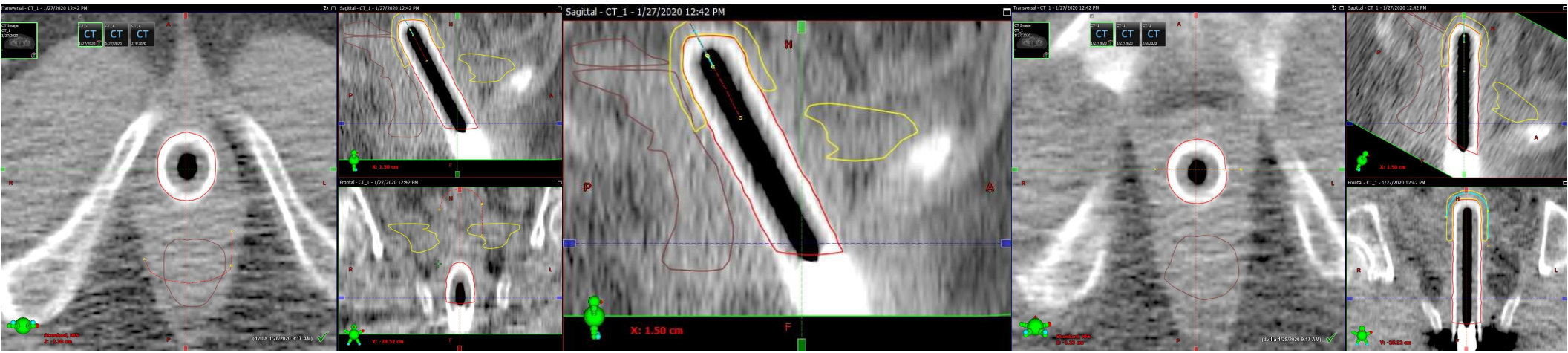

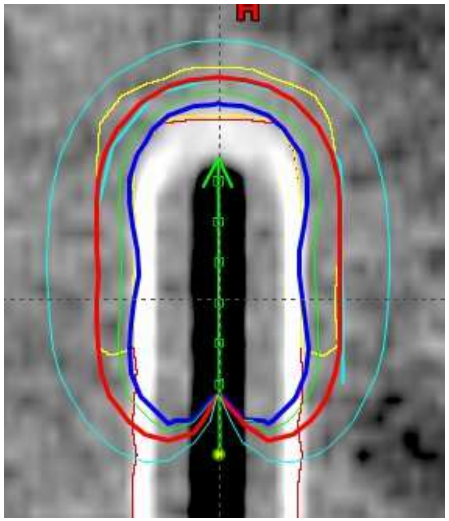

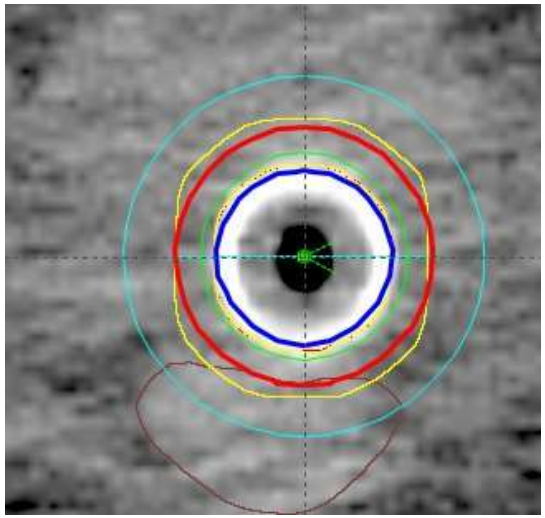

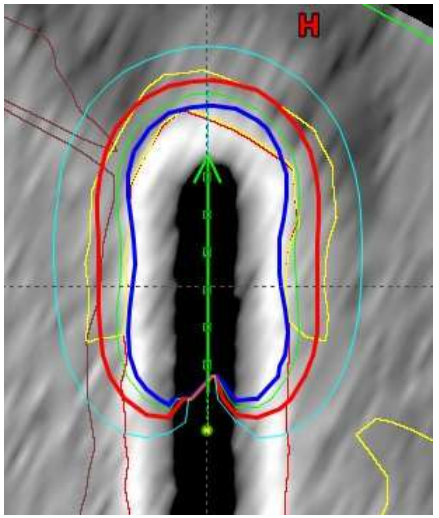

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Journal of Radiotherapy in Practice

cambridge.org/jrp

Original Article

Cite this article: Lozares-Cordero S, Font-Gómez JA, Gandía-Martínez A, Méndez-Villamón A, Villa-Gazulla D, Miranda-Burgos A,

Postoperative endometrial cancer treatments with electronic brachytherapy source

Sergio Lozares-Cordero[1], Jose Antonio Font-Gómez[1], Almudena Gandía-Martínez[1], Agustina Méndez-Villamón[2], David Villa-Gazulla[1], Anabela Miranda-Burgos[2], Verónica Alba-Escorihuela[1] and Sara Jiménez-Puertas[1]

[1]Department of Medical Physics and Radiation Protection, Hospital Universitario Miguel Servet, Zaragoza, Spain and [2]Department of Radiation Oncology, Hospital Universitario Miguel Servet, Zaragoza, Spain

Table 5. Mean values per cylinder size

	%PTV vol.	%PTV vol.
$n=14$		
$d=2.5$ cm	$V_{150\%}$	$V_{200\%}$
Axxent	22.3	2.1
Ir-192	10.9	0.1
Co-60	10.8	0.1
$n=38$		
$d=3$ cm	$V_{150\%}$	$V_{200\%}$
Axxent	19.2	1.8
Ir-192	9.1	0.1
Co-60	6.5	0.0
$n=42$		
$d=3.5$ cm	$V_{150\%}$	$V_{200\%}$
Axxent	16.2	0.5
Ir-192	7.1	0.1
Co-60	8.2	0.2

Abbreviations: n, number of patients; d, cylinder diameter; V_{150} and V_{200}: percentage of the PTV receiving 150% and 200% of the prescribed dose.

Dosimetric results published with 94 patients

- Reduction in dose at D2cc, V35% and V50% in all OAR
- V150, V200 parameters increased in eBT

Table 4. Mean values of dosimetric parameters

PTV	%(PTV vol.)					
$n=94$	Axxent 50 kV	SD	Ir-192	SD	Co-60	SD
$V_{150\%}$	**20.1**	6.0	**8.6**	4.9	**7.7**	4.5
$V_{200\%}$	**1.4**	1.5	**0.1**	0.2	**0.1**	0.2
Bladder						
D_{2cc} (%PD)	**63.8**	17.6	**70.1**	14.3	**68.8**	14.1
$V_{50\%}$ (%vol.)	**7.2**	6.6	**12.7**	9.9	**12.0**	10.8
$V_{35\%}$ (%vol.)	**15.2**	12.1	**28.2**	18.7	**26.1**	17.2
Rectum						
D_{2cc} (%PD)	**61.2**	18.3	**68.4**	16.2	**66.9**	15.5
$V_{50\%}$ (%vol.)	**7.9**	6.4	**14.3**	10.8	**12.8**	10.1
$V_{35\%}$ (%vol.)	**16.7**	11.8	**32.0**	19.3	**29.4**	18.1
Sigmoid colon						
D_{2cc} (%PD)	**48.2**	21.3	**57.8**	18.2	**56.2**	18.4
$V_{50\%}$ (%vol.)	**8.6**	10.8	**16.2**	15.9	**15.8**	17.0
$V_{35\%}$ (%vol.)	**21.1**	20.6	**37.4**	23.5	**34.9**	23.7

Abbreviations: PTV, planning target volume; V_{150} and V_{200}, percentage of the PTV receiving 150% and 200% of the prescribed dose; D_{2cc}, maximum dose of 2 cc; %PD, percentage of the prescribed dose; $V_{50\%}$ and $V_{35\%}$, percentage of organ receiving 50% or 35% of the prescribed dose.

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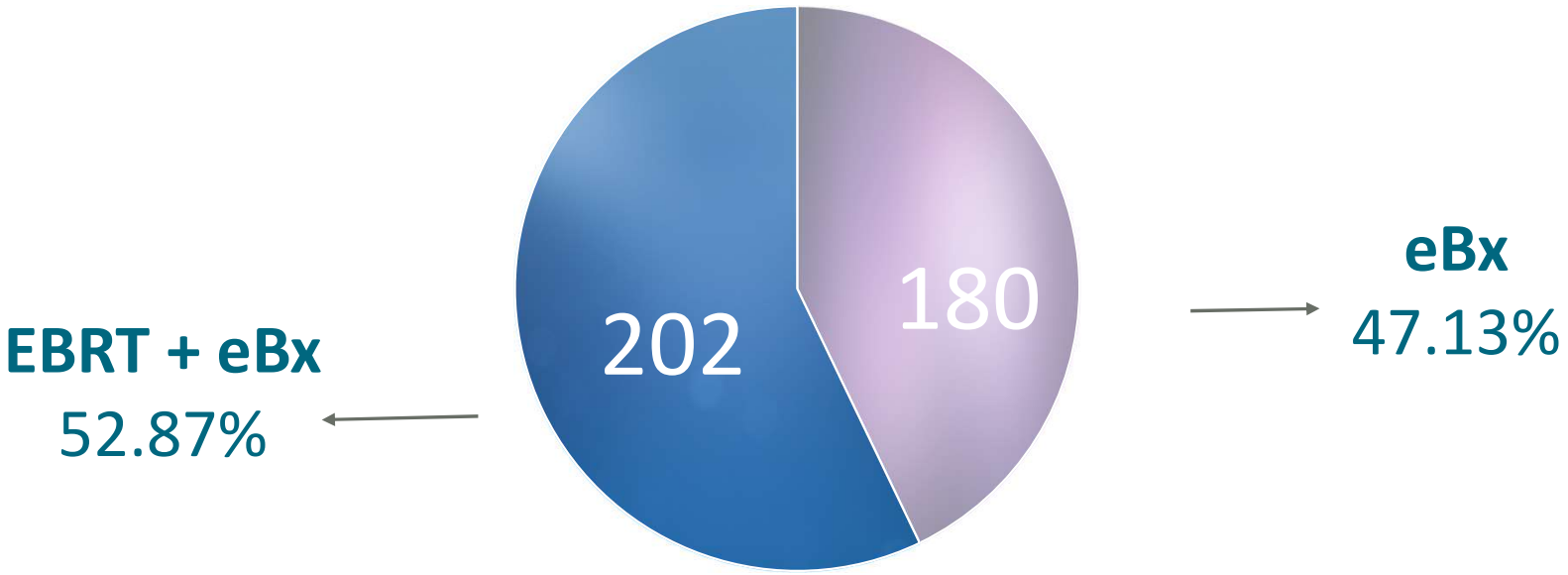
From October 2015 to August 2022 → N=382

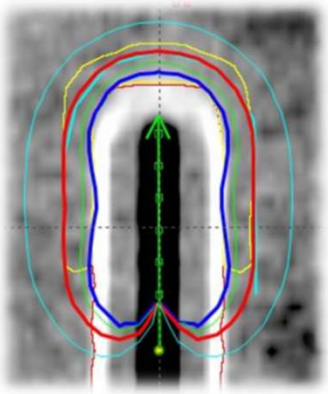


**April/23 N=416 (Boost: 216 y Exclusive: 200)

Endo excl:

500cGy x 5 fr. (2015- 2017)
700cGy x 3 fr. (2017 - now)

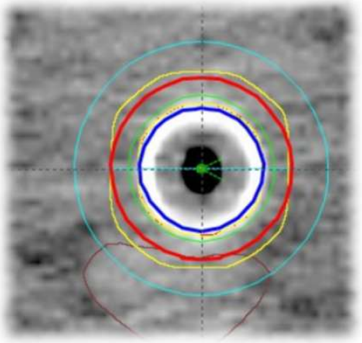
- Median FU 40 months (range 2-75)
- TOT relapses 19 patients (11,5%). 15 LR; 4 Dist
- No Vaginal cuff relapses
- NOT FOUND Acute and chronic toxicity G>2 (CTCAE v.5)



Endo boost:

500cGy x 3 fr. (2015- 2017)
700cGy x 2 fr. (2017 - 2020)
700cGy x 1 fr. (2020 - now)

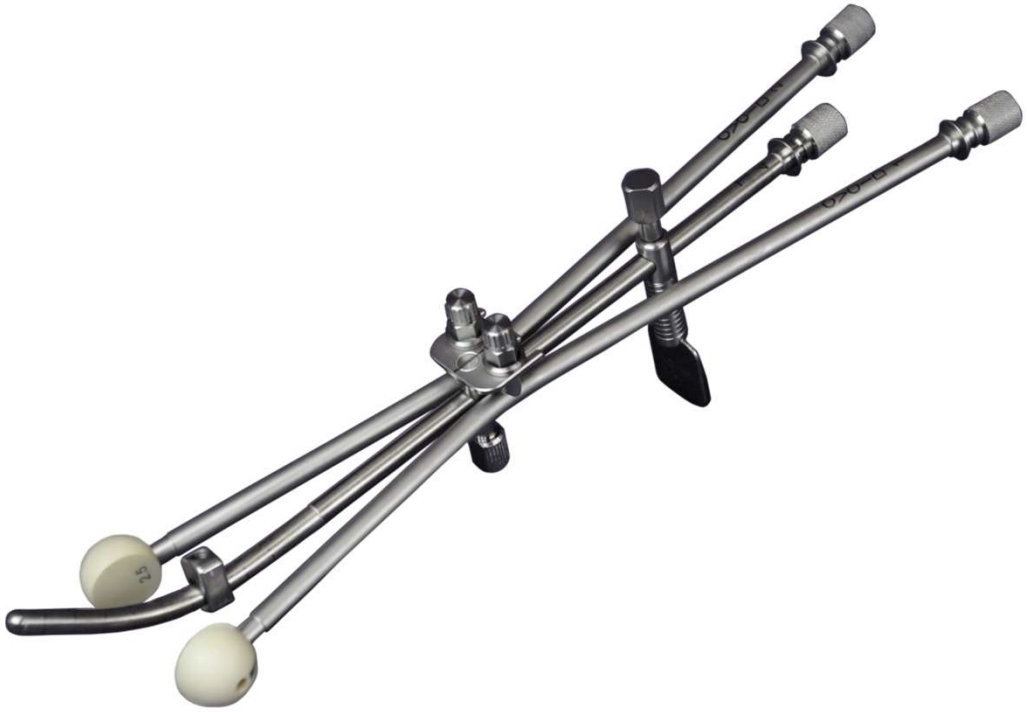
- Median FU 40 months (range 2-60)
- LOC relapses 46 patients (25%). 25 LR; 13 Dist; 1 Vag Cuff (0,5%)
- NOT FOUND Acute and chronic toxicity G>2 (CTCAE v.5)
- NOT FOUND Vaginal and urinary toxicity G ≥ 2
- Gi chronic toxicity G ≥ 2 in 8%



- ✓ **Safe treatment**
- ✓ **High efficacy**
- ✓ **No relevant toxicity**
- ✓ **Lower dose to OARs**
- ✓ **Convenient for staff and patients**

Xoft Cervical Applicator

- The Henschke model applicator can be used to treat cervical cases.
- Intracavitary (IC) treatments, using point A methodology
- Tandem sizes:
  - Tandem angles: 0, 15, 30 and 45 degrees
  - Ovoids diameter: 20 mm, 25 mm and 30 mm



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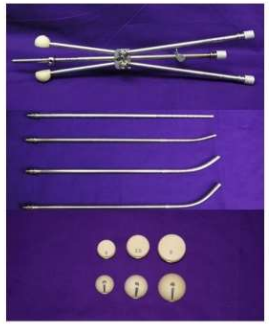
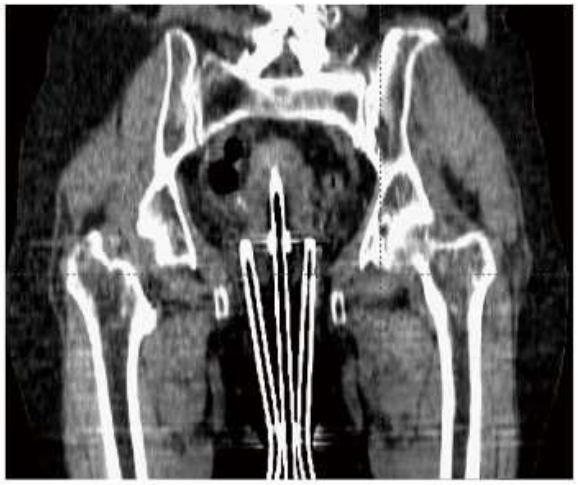
Cervical application

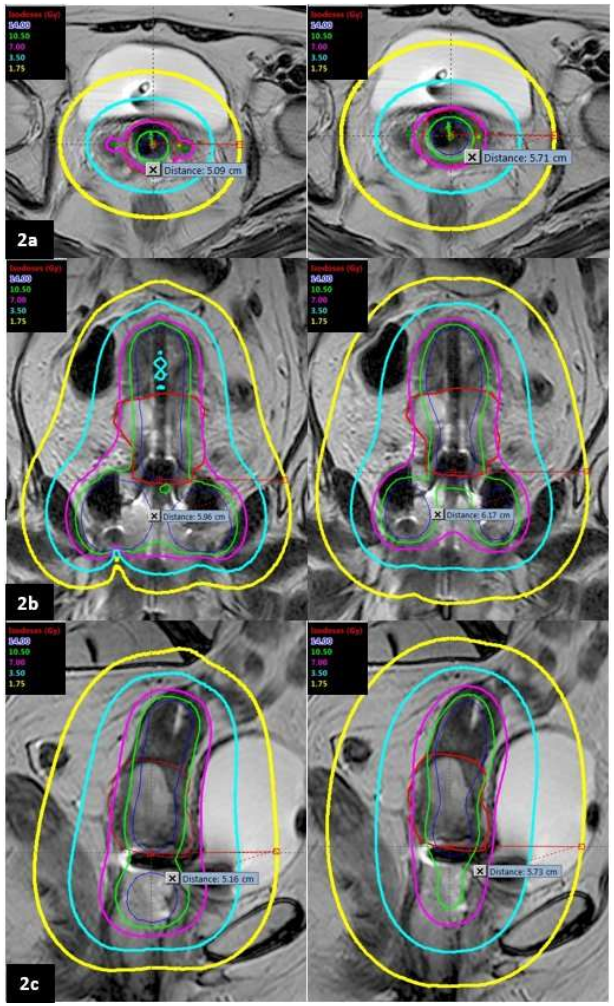
Cervical Applicator

- Henschke style applicator
- Titanium design: 0.41 mm wall thickness
  - CT compatible
  - MR compatibility (1.5T)
  - Length: 336 mm
  - Minimum I.D.: 5.59 mm
- Multiple tandem angles
  - 0°
  - 15°
  - 30°
  - 45°
- Multiple ovoid diameters*
  - 2.0 cm
  - 2.5 cm
  - 3.0 cm

*Unshielded







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JOURNAL OF APPLIED CLINICAL
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Treatment of cervical cancer with electronic brachytherapy

Sergio Lozares-Cordero, José Antonio Font-Gómez, Almudena Gandía-Martínez, Anabela Miranda-Burgos, Agustina Méndez-Villamón, David Villa-Gazulla, Verónica Alba-Escorihuela, Sara Jiménez-Puertas.

Reference	Summary	Findings
Journal of Applied Clinical Medical Physics June 2019	▪ First results of treatment with the Axxent eBT device are promising, as no recurrences have been observed and toxicity is low. eBT is a good alternative for treating cervical cancer in centers without access to conventional HDR.	▪ 8 cervical cancer patients ▪ Delivered a lower dose of radiation to surrounding healthy organs at risk ▪ Very few cases of acute toxicity associated with Xoft

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BRACHYTHERAPY

Feasibility of electronic brachytherapy in cervix cancer–A dosimetric comparison of different brachytherapy techniques

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Table 1
Study patients divided by stage

Stage	Patients
IB+IIA	7
IIB	17
IIIB+IIIC	20
IVA+IVB	4
Total	48
Average HR-CTV (cc)	44.2 ± 25.2

Table 6
Comparative analysis of stages in EMBRACE and the present study

	Study	EMBRACE
IB	12.5%	18.1%
IIA	2.1%	5.1%
IIB	35.4%	51.7%
IIIA	0.0%	1.0%
IIIB	16.7%	14.2%
IIIC	25.0%	0.0%
IV	8.3%	9.8%
Total patients	48	1341

Table 2
Degree of compliance with acceptance criteria by FIGO stage

Stage	Patients	Good (%)	Acceptable (%)	Poor (%)
IB+IIA	14.6%	7 (100%)	0 (0%)	0 (0%)
IIB	35.4%	12 (70.6%)	4 (23.5%)	1 (5.9%)
IIIB+IIIC	41.7%	11 (55%)	2 (10%)	7 (35%)
IVA+IVB	8.3%	1 (25%)	1 (25%)	2 (50%)
Total	**100.0%**	**31 (64.6%)**	**7 (14.6%)**	**10 (20.8%)**

If we compare HR-CTV volume and the validity of the plan, we find that for volumes lower than 30 cc, all the plans are good (92.3%) or acceptable (7.7%), and that for volumes greater than 30 cc, the plans are good in 54.3% of cases and good or acceptable in 71.4%.

79,2% plans with optimal dosimetry

I + II 95,8%, 74.9% Embrace pt profile

5,1 needles vs. “poor” eBx

Hope for everyone
dealing with cancer.