

Improving Breast Conserving Surgery Using the Faxitron® OR Specimen Radiography System – A Complication Analysis, Cost Evaluation and Literature Review

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Abstract. *Background/Aim: The combination of pre-surgical clip placement and hook-wire guided surgery is considered the gold standard for adequately locating non-palpable lesions during breast conserving surgery. After surgical removal of the segment, radiography is required to confirm clip removal, increasing surgical time, post-surgical complication rates, and cost. Patients and Methods: We performed a retrospective analysis, using the Faxitron® in-theater specimen radiography system, of the following primary endpoints: surgical time and complication rates. The secondary endpoints were cost effectiveness and clip-location rates. The Control cohort included breast conserving surgery patients prior to May 2019 (n=150) and the Validation cohort included breast conserving surgery patients after May 2019 (n=53). Results: The analysis showed an improvement in surgical time when using the Faxitron® system, which is directly linked to a benefit in cost effectiveness. A numerical benefit in complication rates was also shown. A subgroup analysis showed a significant advantage in surgical time for breast conserving surgery plus sentinel node biopsy and open breast biopsies. Conclusion: Use of the Faxitron® system significantly reduces surgical time, which increases cost efficiency while maintaining a low complication rate.*

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In modern breast cancer treatment, breast conserving surgery (BCS) is the standard of surgical care. For this surgical method to be performed proficiently, *i.e.*, oncologically sound as well as cost- and time-effectively, an adequate location method needs to be available, especially for nonpalpable lesions (1). Generally, this is performed either by hook-wire marking through ultrasound or by a variety of x-ray-based methods such as mammography. However, tomosynthesis, computed tomography (CT) scans and non-x-ray methods such as MRI, may also be used. Note that there is currently a strong movement away from hook-wire marking using devices such as RFID (Radiofrequency identification) chips (2-4) and magnetic seed (5-10) for example, although currently, hook wire placement for clip location may still be considered the gold standard. These new methods have the benefit that no intraoperative imaging is required in order to prove that the clip has been excised with the specimen. As the current gold standard still relies on intra-surgical imaging, several trials aimed at improving surgical time, clean margin rates and re-excision rates through in theater-imaging systems.

Once a segment is marked, the patient undergoes surgery, and the resected tissue is then evaluated *via* intra-surgical imaging. The method used is generally the same method which was used to introduce the hook-wire system. This is true for most surgeries except preoperative MRI marking. There are several studies on the analysis of intraoperative imaging aiming to improve factors such as surgical time, resection margins and number of re-excision (11). However, there is a general lack of subgroup analyses throughout the available literature pertaining to the cost effectiveness of intra-surgical imaging. Most commonly, trials evaluated the effect

Table I. Overview of the published articles from the year 2010 onwards.

Author	Year	Study design	Number of cases	Analyzed parameters	Result
Mariscotti <i>et al.</i> (13)	2020	Retrospective	267 (129 SSM, 138 IDSM)	OR time, re-excision rate	Reduced OR time (sig.), re-excision rate equal
Miller <i>et al.</i> (24)	2016	Prospective, randomized	72 (36 SSM, 36 IDSM + SSM)	OR time, target lesion, margins	No difference
Majdak-Paredes <i>et al.</i> (23)	2015	Retrospective	98 IDSM	Margins	Low rate of incomplete excisions
Ihrai <i>et. al.</i> (25)	2014	Prospective	170 IDSM	Margins	Accuracy dependent on histology; limited for high-density
Wang <i>et al.</i> (22)	2014	Retrospective	100 IDSM + SSM	Image quality, target lesion	Lower image quality, high diagnostic confidence
Camp <i>et al.</i> (20)	2013	Retrospective	344 (230 SSM, 114 IDSM)	OR time	Reduced OR time (sig.)
Kim <i>et al.</i> (1)	2013	Retrospective	201 (105 SSM, 96 IDSM)	OR time, margins	OR time similar, fewer positive margins
Layfield <i>et al.</i> (21)	2012	Retrospective	224 (111 without radiography, 113 IDSM)	Specimen weight, re-excision rate	Reduction of specimen weight (sig.), re-excision rate equal
Bathla <i>et al.</i> (18)	2011	Retrospective	131 IDSM	Margins	Can decrease rate of positive margins

SSM: Standard specimen mammography; IDSM: intraoperative digital specimen mammography.

of in-theatre imaging onto surgical margins, reoperation rates and duration of the surgical intervention in a breast surgery environment (11-15), for both invasive and DCIS (ductal carcinoma *in situ*) lesions (16-19). There are no data on improvement of surgical time in a German health care environment. Note that even without in-theatre imaging, modern high-end surgical theaters are able to quickly evaluate specimens during surgery (20-22), resulting in only marginal surgical time reduction for most cases. Overall, this topic has largely been retrospectively evaluated although a single prospective trial in 2016 showed no difference in surgical time and clean margin resections. Results from the retrospective analyses trials seem to show a slight improvement in surgical time and or better margin safety (23). In summary, in-theater and intraoperative imaging may improve margins and decrease re-excision rates (Table I). While a prospective trial failed to show a benefit (24), more data needs to be accumulated in order to produce material for meta-analyses.

This work will therefore focus on non-palpable lesions that had been previously marked using an x-ray method, in this case mammography, during a type of breast conserving surgery and/or mastectomy procedure. We collected real-world data with the Faxitron® system in a German health care system environment. This trail aimed to expand and elaborate on the available in-theater imaging data. The analyzed endpoints were surgical time, with an analysis of surgical time improvement by type of surgery, complication rates and cost effectiveness analysis.

Four main hypotheses were evaluated: 1) Using a Faxitron® system, surgical time will decrease since immediate feedback can be given to the surgeon. 2) A decrease in surgical time will be inversely proportional to surgical complexity. 3) A decreased surgical time correlates to a decrease in complication rates. 4) Cost-effectiveness can be reached after a set number of surgeries.

Patients and Methods

This is a single center, retrospective, multi-surgeon, cohort analysis with consecutive recruiting. In May 2019, the Breast Cancer Center of the Department of Gynecology and Obstetrics at the University of Cologne, Germany began implementing the Faxitron® HD Specimen Radiography System (Hologic, Inc., Marlborough, MA, USA) which allows an on-site, in-theater, x-ray-based evaluation of removed breast tissue segments. Patients from April 2017 until May 2019 were considered the standard control cohort. The Faxitron® cohort included patients from May 2019 until March 2020. Due to the size of the university campus, radiological evaluation of the sample takes anywhere between 20 to 45 min due to geographical and logistical reasons. This being the case, it was assumed that the introduction of the Faxitron® OR (operating room) system would drastically reduce surgical time, leading to a better use of available OR capacities.

Trial recruitment was to be 3:1. We recruited 150 cases in the control cohort and 53 cases in the Faxitron® cohort. All types of surgery had to be preoperatively marked by a hook wire using a mammography-based method as a Standard titanium clip had been placed at times of biopsy. A specimen was considered excised successfully when the clip was confirmed by an x-ray method.

Table II. Patient characteristics, type of surgery, tumor characteristics and type of wire localization.

	Standard		Faxitron™		p-Value
		%		%	
Number of cases (n)	150		53		
Age in years*	54±11		57±12		0.106**
Type of surgery					0.678***
BCS	40	26.7	10	18.9	
BCS+AD	19	12.7	5	9.4	
BCS+SLNB	59	39.3	23	43.4	
Diagnostic excision	27	18.0	14	26.4	
Re-excision	1	0.7	0	0	
NSM	2	1.3	0	0	
NSM+SLNB	2	1.3	1	1.9	
Histology					0.583***
Invasive	75	50.0	23	43.4	
<i>In situ</i> ductal carcinoma	27	18.0	8	15.1	
Other tumors	21	14.0	8	15.1	
Benign	27	18.0	14	26.4	
Type of wire localization					0.788***
Ultrasound-guided	43	28.7	18	33.9	
Mammography-guided	101	67.3	34	64.2	
Magnetic resonance-guided	5	3.3	1	1.9	
Without	1	0.7	0	0	

*Mean±standard deviation; **t-test (two-tailed); ***chi-squared test. BCS: Breast conserving surgery; AD: axillary dissection; SLNB: sentinel lymph node biopsy; NSM: nipple sparing mastectomy.

Data collection. The retrospective nature of this work required to use patient and surgical data found in patient files, histopathological and radiological reports, surgical report, and oncological conferences. After data acquisition patient identifiers were removed for purposes of publication. Data analysis was performed by the authors EC, WA, KB and WM. Data compilation was performed by WA.

Inclusion criteria. Any non-palpable lesion that had previously been titanium clip- and hook-wire marked. Any type of surgery. Surgeries that were allowed to be evaluated, were open re-excision and open breast biopsy, breast conserving surgery, if wire marked, and subcutaneous mastectomy.

Exclusion criteria. Palpable lesions and lesions that had not been previously marked by titanium clips. The analysis focuses on breast conserving surgery and open biopsy surgery since these are comparable in complexity. For descriptive reasons only, we decided to also introduce a rare case of a subcutaneous mastectomy being hook-wire marked in order to evaluate whether or not a benefit can be observed. Only 1 case was evaluated in the Faxitron® group vs. 2 cases in the control group. Due to the consecutive nature of patient recruitment, we were not able to focus on one type of surgery, thus a certain amount of heterogeneity was introduced. On the other hand, this allowed for a subgroup analysis regarding surgical complexity.

Cohorts. Table II shows a representation of the control (standard) cohort versus the Faxitron® cohort. There was no statistically significant difference in age and types of surgery. The percentage of subcutaneous mastectomies was 2.6% for the Control cohort and

1.9% for the Faxitron® cohort. Lumpectomies were performed without (open biopsy and DCIS) and with axillary dissection (invasive disease). Axillary dissection was divided into full axillary dissection or sentinel node biopsy. This was deemed necessary as a subgroup analysis of procedure dependent-surgical time was thought to correlate with the complexity of the surgery. Naturally, this decreased subgroup size. Tumor subtypes did not differ significantly with 50% being invasive carcinoma and 18% being DCIS lesions (Control) compared to 43.4 and 15.1% in the Faxitron® group (Table II). Benign lesions were also evaluated, as all non-palpable lesions were included even of no prior histology, or insufficient prior histology had been obtained.

The type of method used for intra-surgical wire/clip localization was mammography/Faxitron®. Presurgical hook wire placement was mostly performed by mammography; in case of a clearly visible clips, ultrasound wire placement was also acceptable. In 3% and 2% of the respective cohorts, MRI was used in order to locate the clip preoperatively. This was necessary as MRI was also used to determine the presence of a possible second lesion. The latter was not evaluated in this study.

Endpoints. Primary endpoints were surgical time (Table III) and complication rates (Table IV) as well as clip-localization rates. Secondary endpoints were cost effectiveness and clean margin rates (Table V and Figure 1).

Surgical procedures. All surgeries were performed by experienced surgeons. There were no conflicting surgical trials recruiting at the same time. All surgeries were being performed to gold standard. Surgical times in the control cohort as well as the Faxitron® cohort

Table III. Operative time.

	Standard		Faxitron™		p-Value***
	Number of cases (n)*	Time in minutes**	Number of cases (n)*	Time in minutes**	
Overall	138	49±20	50	42±16	0.012
Type of surgery					
BCS	37	39±16	10	35±10	0.231
BCS+AD	17	66±23	5	61±18	0.323
BCS+SLNB	54	56±18	21	48±14	0.029
Diagnostic excision	27	38±16	13	28±7	0.034
Re-excision	1	36	0	-	
NSM	1	58	0	-	
NSM+SLNB	1	59	1	62	

*Only cases with unilateral breast surgery + specimen radiography were taken into account; **Mean±standard deviation; ***t-Test (one-tailed). BCS: Breast conserving surgery; AD: axillary dissection; SLNB: sentinel lymph node biopsy; NSM: nipple sparing mastectomy.

were obtained from the raw data included in the surgical reports. This was deemed appropriate, as the goal was to quantify a possible net difference in surgical time.

Statistics. The statistical calculations of the data were performed by VassarStats (Vassar College, Poughkeepsie, NY, USA) and Excel. Pearson’s chi Quadrat Tests and t-tests were performed when appropriate.

Ethics committee approval. Informed consent for the surgical procedures was provided by all patients involved in this study. This study was conducted in accordance with institutional review board standard operation procedures. Ethics committee approval was deemed unnecessary due to the retrospective nature of the analysis by the ethics committee of the University of Cologne, Cologne, Germany (File Number 20-1486 -13.01.2021)

Results

Primary endpoints. Surgical time relative to surgical procedure showed interesting results. A statistically significant time benefit could only be demonstrated for diagnostic excisions where 27 patients had a surgical time of 38±16 min for the standard cohort and 13 patients had a surgical time of 28±7 (Faxitron®). This 10-min difference was statistically significant (p=0.034). A similar 8-min benefit was observed for breast conserving surgery with sentinel node biopsy, where 54 patients had a surgical time of 56±18 min in the standard cohort versus the Faxitron® group where 21 patients displayed a surgical time of 48±14 min. The time difference was also statistically significant (p=0.029).

Interestingly, for breast conserving surgery alone, i.e., for DCIS only, this 10-min benefit could not be reproduced. The same was true for a breast conserving surgery plus axillary dissection scenario. However, a numerical benefit of 4 min for the BCS alone and 5 min for the BCS plus axillary

dissection was demonstrated favoring the Faxitron® scenario. Due to low patient numbers these trends are currently only descriptive in nature, and one may assume that this numerical trend would reach significance with larger numbers. Data for re-excision and subcutaneous mastectomy are only descriptive in nature and were mostly included in the analysis for reasons of complete data representation. An overview is shown in Table III.

Previous trials argued that specimen weight might differ as the tendency towards a decreased surgical aggressiveness may present itself with in-theater control of the margins. Therefore, surgical specimen weight was analyzed, and no significant difference was observed. These data are shown in Table VI. Inversely this was thought to result in different clip location rates. However, clip location rates were 100% for both cohorts. In conclusion, no difference in clip location rates and sample weight/size was demonstrated.

The initial hypothesis that a decrease in surgical time might translate into a decreased post-surgical complication rate was also evaluated. However, no benefit was shown. Across all available patients we found no complications for 105 patients (79.55 %) of the control group compared to no complications in 39 patients (82.98%) of the Faxitron® group. This slight numerical difference was not significant. Overall, the improvement in surgical time did not translate into the improvement in complication rates. An overview is shown in Table IV.

Secondary endpoints. This dataset evaluated clean-margin rates and cost-effectiveness. The re-excision rate was 13% for the standard arm and 10% for the Faxitron® arm, which is comparable to literature. Again, the trend favors the in-theater specimen evaluation, however, a statistical significance was not achieved. The data are shown in Table V.

Table IV. *Postoperative complications.*

	Standard		Faxitron™		<i>p</i> -Value*
		%		%	
Number of cases (n)**	132		47		0.610
Complications	27	20.45	8	17.02	
No complications	105	79.55	39	82.98	
Type of complication***					0.536
Seroma	16	59.3	4	50.0	
Infected seroma	0	0	1	12.5	
Hematoma	6	22.2	2	25.0	
Suture dehiscence	3	11.1	1	12.5	
Infection of the wound	1	3.7	0	0	
Exanthema	1	3.7	0	0	
Type of intervention***					0.209
Puncture	13	48.2	3	37.5	
Puncture + Antibiosis	0	0	1	12.5	
Conservative	11	40.7	4	50.0	
Secondary suture	3	11.1	0	0	

*Chi-squared test; **Only those cases were taken into account for which a statement on postoperative complications was available; ***Only those cases in which a complication occurred were considered.

Table V. *Margins.*

	Standard		Faxitron™		<i>p</i> -Value*
		%		%	
Number of cases (n)**	123		39		0.649
R0	107	87.0	35	90.0	
R1	16	13.0	4	10.0	

*Chi-squared test; **Only those cases were taken into account for which a statement of the resection margin was available.

Table VI. *Specimen weight.*

	Standard		Faxitron™		<i>p</i> -Value***
	Number of cases (n)*	Weight in gram**	Number of cases (n)*	Weight in gram**	
Overall	108	31±69	45	25±35	0.596
Histology					
Invasive	53	26±32	21	23±38	0.848
<i>In situ</i> ductal carcinoma	21	44±106	6	61±43	0.626
Other tumors	13	65±123	8	25±19	0.424
Benign	21	12±9	10	9±3	0.316

*Only those cases were taken into account, in which a statement of specimen weight was available; **Mean±standard deviation; ****t*-test (two-tailed).

More interestingly however, we were able to demonstrate cost-effectiveness. In order to compare cost-effectiveness, we counterbalanced the procurement of the Faxitron® system at approximately 95.000 Euros, a high initial cost of

operation. We calculated average costs of surgical/OR time and the personnel used to evaluate and transport any given specimen. Obviously, physically moving a surgical specimen from the surgical theater in one location to the

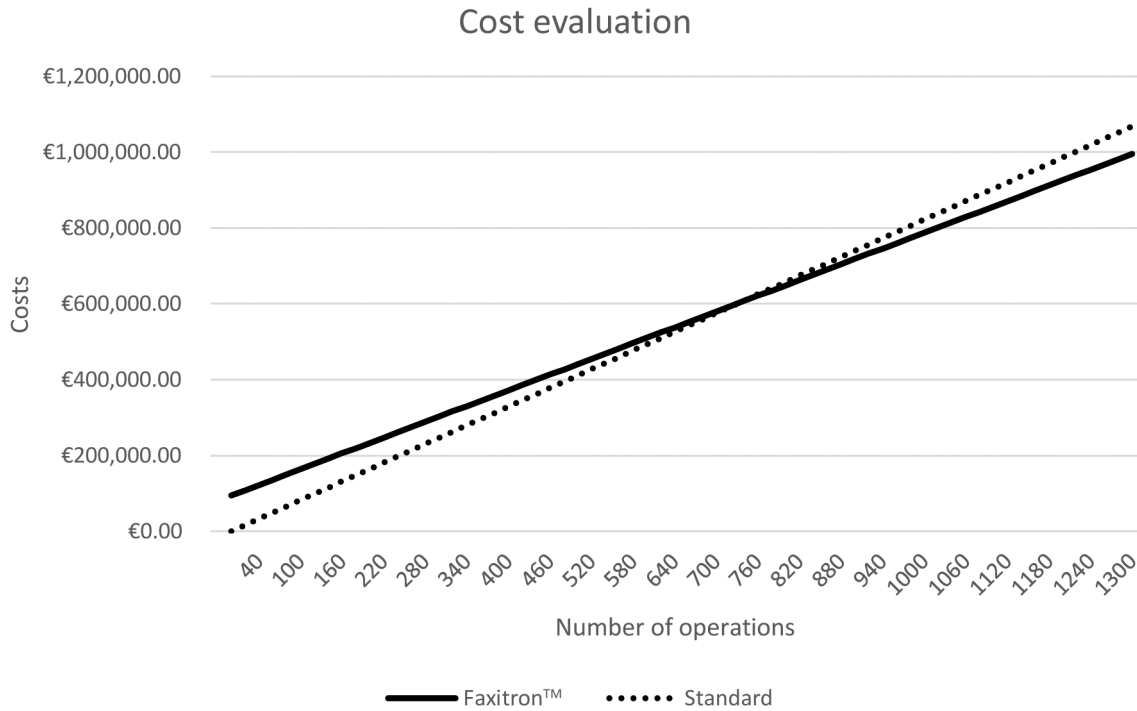


Figure 1. Cost evaluation. Solid line: Operating costs with the Faxitron system. Dotted line: Operating cost without the use of the Faxitron System.

radiology department in another location, requires manpower and increases surgical time. When an in-theater system is used, no additional personnel is required for transporting the specimen and performing a radiography, since all the above was performed by the OR team. A single minute of surgical time was evaluated at approx. 16 €, to which the time adjusted personnel cost, as mentioned above, was added. A detailed calculation may be obtained from the authors. Estimation was extremely conservative. Actual Faxitron® procurement costs might be a lot lower, also personnel cost tends to be a lot higher. Overall, we were, however, able to save 128,94 € per surgery using the Faxitron® system on average - especially since cost-effectiveness is based on a reduction in surgical-time and a reduction in personnel costs. Thus, at the assumed cost of system procurement stated above, 734 surgeries were needed to be performed to benefit from the use of this in-theater system. For our center, operating at maximum capacity the breakeven point was reached after three years of operation.

The Faxitron® system requires two main factors in order to operate cost-effectively. These factors are a significant geographical distance between operating theater and the evaluating radiologists and a high number of surgeries. Thus, the Faxitron® system seems to be most valuable for large breast cancer centers.

Discussion

The majority of data available shows that there might be a decrease in surgical time when an in-theater radiography system is used. However, data remains heterogeneous. A single prospective randomized trial showed no difference in surgical time, clean margin rate and target lesion location. Our trial thus further broadens the available database with the hypothesis that we would be able to improve surgical time and work cost-effectively using this in-theater radiographic system. Simple breast conserving surgery plus sentinel node biopsy as well as open biopsy surgeries show an approximate 10-min benefit. As surgical complexity increases, *i.e.*, when axillary dissection is performed, this time benefit decreases and is no longer statistically significant. Since, in addition, no difference in clip-location rate, clean margin rate and complication rates can be achieved with an in-theater radiography system one might argue that this system does not yield any benefit other than this marginal OR time-decrease. The similar complication rates for both cohorts may be explained since a OR time decrease is not necessarily equal to a decrease in open-wound time. It is merely a decrease in the time the patient is anesthetized, since within the evaluated surgical theater, wounds were closed before information of clip location is conveyed to us. Secondary reopening of the surgical situs is of course never the case if an immediate evaluation of the specimen is possible.

Despite only a marginal time benefit, we argue that in-theater specimen evaluation is still useful. Results from the surgical subgroup analysis seem plausible, since a decrease in surgical time can only be achieved if a surgery can be finished before radiological evaluation of the specimen is complete. While complex procedures such as an axillary dissection require significant time, so as to allow for a lengthy process of radiological specimen evaluation, fast in-theater evaluation are needed for short procedures. The current trend of oncological surgical interventions for early breast cancer is away from axillary dissection, thus surgeries do become less complex. In addition, we demonstrated that a cost-effective operation of an in-theater radiography is possible even when surgical time remains equal since personnel costs can be reduced. If the operating theater capacity is used to its maximum, we can assume that a decrease in surgical time of up to 10 min several times per day may allow us to perform one extra surgery in this scenario. Adding to this benefit the reduction in personnel cost, we suggest that the Faxitron® system is useful and relevant.

Therefore, the benefit of the system remains threefold: reduction in surgical time for certain surgeries with immediate feedback of target location, increase in the number of surgeries for a high-volume environment and cost-effectiveness due to OR-time and personnel decrease. The hypotheses may be addressed as follows: 1) Using a Faxitron® system, surgical time will decrease since immediate feedback can be given to the surgeon. This is correct for surgeries with low complexity, *i.e.*, BCS+SNL and open biopsy. 2) A decrease in surgical time will be inversely proportional to surgical complexity. This is supported by our data. Especially a cohort where axillary dissection was required the time benefit seems to decrease. 3) A decreased surgical time correlates to a decrease in complication rates. This could not be shown. Complication rates were similar for both cohorts. 4) Cost-effectiveness can be reached after a set number of surgeries. This is true. The break-even point is reached after 3 years of system operation. Driving factors are, procurement cost, personnel cost and reduction in surgical time.

Conclusion

We were able to show that the application of the Faxitron® system is a safe method to intraoperatively evaluate the target lesion *i.e.*, clips within a non-palpable breast lesion. A time benefit was only shown for breast conserving surgery with sentinel node biopsy and open biopsy. Cost-effectiveness depends on several factors, mainly a high-volume surgical environment and a pre-existing geographical distance between the surgical theater and the place of radiological evaluation of the specimen. We recommend in-theater radiological specimen evaluation whenever possible.

Conflicts of Interest

The Authors have no conflicts of interest to declare in relation to this study.

Authors' Contributions

Eichler Christian: Study design, patient treatment, data acquisition, paper writing/editing, data analysis. Westerhoff Anke: Study design, data acquisition, paper writing/editing, data analysis. Warm Mathias, Puppe Julian, Hanstein Bettina: Study design, paper editing, data analysis. Krug Barbara and Malter Wolfram: Study design, patient treatment, data acquisition, paper writing/editing, data analysis.

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