

The Efficacy of the Biopsy Chip Used in the Delivery of Prostate Biopsy Samples on Time Saving

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What's known on the subject? and What does the study add?

Traditional prostate biopsy methods require multiple containers, increasing handling time and potential tissue fragmentation. Innovations like the biopsy chip aim to streamline this process by consolidating samples onto a single platform, improving efficiency. Our study confirms that using a biopsy chip significantly reduces preparation, sectioning, embedding, and microscopic analysis times. While the biopsy procedure itself takes slightly longer, overall workflow efficiency is enhanced. These findings highlight the biopsy chip as a practical tool to optimize pathology processing, reduce workload, and improve diagnostic efficiency in prostate cancer evaluations.

Abstract

Objective: To reduce the workload, it is important to evaluate the prostate biopsy materials separately and in a shorter time. The aim of this study was to align and transfer the prostate biopsy materials taken by urologists on the same chip and to investigate whether the pathologist evaluates the tissues on this chip in a shorter time.

Materials and Methods: This was a prospective, non-randomized, comparative study including patients scheduled for 12-core transrectal ultrasound-guided prostate biopsy. Patients were assigned to one of two groups based on the biopsy specimen delivery method: The BxChip™ group (n=34), in which cores were aligned on a grooved gel-based matrix, and the conventional group (n=31), where each core was placed in a separate tube. The preparation time before biopsy and the total procedure time were recorded by urologists. Pathologists documented macroscopic assessment, sectioning, embedding, and microscopic examination times for each method.

Results: There was no statistically significant difference between the two groups in terms of demographic data and patient characteristics. While the biopsy procedure duration was longer in group 1, the duration of pre-biopsy preparation, macroscopic examination, sectioning, embedding, and microscopic examination was statistically lower in group 1 than in group 2.

Conclusion: In our study, the biopsy chip method is effective and provides time advantages in terms of taking, transferring, and analysing prostate biopsies.

Keywords: Prostate cancer, prostate biopsy processing, multiplex tissue processing, time saving

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Introduction

Prostate cancer ranks as the second most prevalent form of cancer and the fifth highest contributor to cancer-related deaths in males globally (1).

The primary diagnostic tool for prostatic cancer is the histopathologic analysis of prostate core needle biopsy specimens. Ultrasound (US)-guided and/or magnetic resonance imaging (MRI)-targeted biopsies are part of the standard approach according to clinical necessity. A prostate biopsy can be performed by the transperineal or the transrectal approach (2).

For systematic biopsies without prior imaging for targeting, it is recommended to take cores from both sides of the prostate, and the apex to the base in the peripheral gland, reaching as posterior and lateral as possible. As demonstrated by a systematic review published in 2006, a systematic biopsy requires at least 12 cores (3). In the presence of suspicious areas determined by digital rectal examination (DRE) or MRI before biopsy (with more than one core from each MRI-visible lesion) and in cases where saturation repeat biopsy is required (>20 cores), it is recommended to take additional cores (4).

Since the conventional biopsy technique is thought to be time-consuming, new methods are needed. The BxChip™ is one of the techniques developed for this purpose. The BxChip™ technique aims to more quickly and reliably generate multiplex biopsy arrays using a matrix material and to use the arrays in histological procedures (5).

Preliminary data on the impact of the BxChip™ technique considers that it is easy to implement, has a rapid learning curve, and reduces the processing time of the ever-increasing number of cores per patient collected during prostate biopsy (6).

In this study, we aimed to evaluate the chip method using multiplex biopsy in prostate biopsies performed by urologists in our clinic and the time advantages it provides in the pre- and post-biopsy diagnostic periods.

Materials and Methods

This was a prospective, non-randomized, comparative study. The study was conducted in accordance with the principles of the Declaration of Helsinki, after obtaining approval from the İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine Clinical Research Ethics Committee (IRB number: 83045809-604.01.02, date: 17.05.2019) and detailed informed consent from all patients. An a priori power analysis revealed that a sample size of n=28 per group was needed to detect a significant difference [two-sided $\alpha=0.05$, power $(1-\beta)=90\%$, effect size=0.8].

Patients were included in the study if they were scheduled for a 12-core transrectal US (TRUS)-guided prostate biopsy

between January 1, 2020, and January 31, 2023, undergoing the procedure for the first time, had negative multiparametric prostate MRI findings (Prostate Imaging Reporting and Data System ≤ 2), but still considered at clinical risk for prostate cancer based on serum prostate-specific antigen (PSA) level, PSA density, DRE findings, or family history,

Patients were assigned to one of two groups according to the technique used to deliver biopsy specimens to the pathology department. This allocation was non-randomized and was based on the availability of biopsy chips at the time of the procedure. Due to the differences in specimen handling, blinding of urologists and pathologists was not feasible.

In 34 patients (group 1), a multidirectional grooved matrix made of Biopsy Chip, a tissue surrogate gel, was used by the urologist to align the biopsy cores. The samples were then delivered to the pathology laboratory using this chip. In 31 patients (group 2), each biopsy core was placed in a separate standard biopsy container, and the samples were transferred to the pathology department using the conventional method. This was a prospective, non-randomized comparative study.

Biopsy Procedure

Biopsies were performed in the endoscopy suite of our institution with a team of one experienced urologist who had more than five years of experience in prostate biopsies, one nurse, and one ancillary staff member. Patients in both groups were started on antibiotic prophylaxis the day before the procedure and were directed to self-administer a sodium phosphate enema the night before. Just before the procedure, urine culture results, blood coagulation parameters, antiaggregant or anticoagulant drug use, and the presence of specific infection symptoms (e.g., fever, chills, urgency, frequent urination, or suprapubic tenderness) were thoroughly reviewed by urologists.

The patients were placed in the left lateral decubitus position, and lubricant sterile gel with lidocaine (Lubagel Plus, Yasemin Medika, İstanbul, Türkiye) was applied via the rectal route. A DRE was performed. The urologists used TRUS with a multiplanar 6.5 MHz probe attached to the US scanner (Siemens Medical Systems, Inc., Issaquah, WA, USA). A periprostatic block was applied under the guidance of TRUS, with a combination of lidocaine and bupivacaine using a 20-cm long, 22-gauge needle (Chiba Biopsy Needle with Echogenic Tip, Argon Medical Devices Inc., Dallas, USA), for both sides. Prostate volume was calculated using the prostate ellipsoid formula: volume (V)= $0.52 \times (L \times W \times H)$, where L is the cephalocaudal diameter, W is the width, and H is the anteroposterior diameter. TRUS-guided prostate biopsy was performed with a disposable 18-gaugex25-cm biopsy needle (Argon Pro-Mag Biopsy Needle, Argon Medical Devices Inc., Dallas, USA). Twelve cores were taken and put into separate containers in the

conventional biopsy arm (Figure 1) and placed in two separate containers in the BxChip™ arm (Figure 2).

1. Conventional Preembedding Method

Traditionally, the recommended method for processing biopsy samples is by embedding them individually in a supporting material such as a paraffin block. The individual samples' paraffin blocks are then divided into thin sections using a microtome. These thin sections are then placed on a microscope slide, stained as necessary, and examined under a microscope. One runs the risk of failing to include the tissue sample when sectioning the paraffin blocks and losing too much of the sample before a complete section is produced. The standard biopsy technique results in a large number of paraffin blocks, necessitating numerous sections and slides, high costs for consumables, processing labor, and pathologists' time to interpret the slides.



Figure 1. Twelve separate containers in conventional biopsy procedure

2. BxChip™ Method, Histologic Work-up and Diagnosis

The BxChip™ consists of a custom-made matrix that easily receives and holds multiple tissue cores. This block of matrix material is used to create a multiplex biopsy array, a histological preparation, with cell or tissue samples arranged within it. The chip is a proprietary biomimetic protein polymer that has a grooved, sectionable 2 mm, matrix. During both grossing and biopsy procedures, it can be utilized to align the specimens. One individual sectionable matrix can accommodate up to 12 core biopsies for simultaneous processing and sectioning. The chip, loaded with cores, is sandwiched between two foam pads in a tissue cassette to prevent any movement during processing. The biomimetic polymer shrinks during processing to the same extent as the cores themselves, which provides immobilization. Upon tissue processing, the chip is embedded and the paraffin block is sectioned.

Statistical Analysis

Statistical analysis of all data was performed using SPSS Statistics (Version 21.0, IBM Corp.). The suitability of the quantitative data for normal and non-normal distributions was assessed using the Kolmogorov-Smirnov test. The Mann-Whitney U test was used to compare non-normally distributed data, while the independent samples t-test was applied for normally distributed variables. A p-value of <0.05 was considered statistically significant for all analyses. An a priori power analysis was conducted using G*Power software (version 3.1.9.7, Düsseldorf, Germany). Assuming a two-tailed $\alpha=0.05$, power $(1-\beta)=0.90$, and an effect size of Cohen's $d=0.8$, the analysis revealed that a minimum of 28 participants per group was required to detect a statistically significant difference.

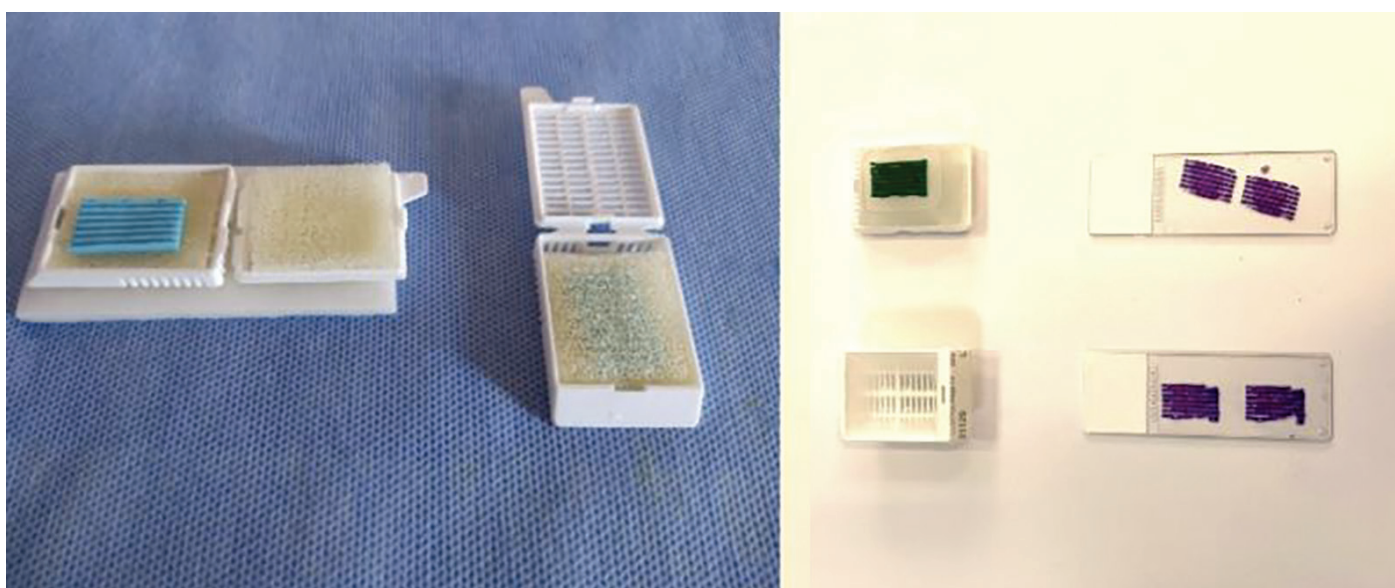


Figure 2. BxChip™ container allows to align 6 biopsy cores

Results

TRUS-guided biopsy has been successfully performed in 65 cases. Prostate biopsy samples were collected using the biopsy chip and the traditional method in 34 and 31 patients, respectively.

Groups were similar in terms of median age, PSA, PSA density, and prostate volume. The median age was 66.5 years and 69 years for group 1 and group 2, respectively. The median PSA levels were 7.27 ng/mL for group 1 and 7.5 ng/mL for group 2; PSA densities were 0.16 for group 1 and 0.13 for group 2, respectively. The median prostate volumes were 52 and 56 cc for groups 1 and 2, respectively (Table 1).

The median duration of pre-biopsy preparation was 3.5 (3.2-3.7) minutes and 4.3 (3.5-5.8) minutes in groups 1 and 2, respectively ($p<0.001$). The median duration of the biopsy procedure was 4.25 (3.7-5.2) and 3.96 (3.3-4.6) minutes in group 1 and 2, respectively ($p<0.05$). After the biopsy materials were delivered to the department of pathology, the median duration of macroscopic examination was 2.25 (1.5-2.2) and 5.27 (4.5-6.1) minutes in group 1 and group 2, respectively ($p<0.001$). The median duration of sectioning was 5.29 (3.5-7.9) and 12 (10-12.4) minutes in groups 1 and 2, respectively ($p<0.001$). The median duration of embedding is 2.2 (1.3-9.0) and 11 (9.2-16.2) minutes in groups 1 and 2, respectively ($p<0.001$). The median duration of microscopic examination was 12.29 (6.9-15.3) and 15 (9.4-17.3) minutes in group 1 and 2, respectively. There was no statistically significant difference in the median duration

of microscopic examination between the groups ($p=0.143$) (Table 2).

Discussion

TRUS-guided prostate biopsy represents the benchmark procedure in pathological diagnosis of prostate cancer (2). The conventional method involves the placement of each biopsy sample in a distinct container. Following this procedure, each core must be examined individually by the pathologist. All these processes are considered time-consuming. In a study that evaluated the use of multicompartiment microcassette in prostate biopsy, 88 patients underwent TRUS-guided prostate biopsy. The time saved per case was determined to be 20 minutes (72%) on average (7). Our study demonstrated similar results, as the overall average time saved per case was 21.75 minutes (42%).

In another study, the evaluation of the test time involved 48 prostate specimens. Two sets of sextant biopsies were obtained *ex vivo*. For each specimen, one set was obtained with the standard protocol which involves fixing each biopsy core in separate containers, and the other one was acquired using a multiplex chip. Time reduction was observed in the multiplex chip arm of the study (8). One notable distinction between our study and the aforementioned study is that the latter, was *ex vivo*.

These two studies mentioned above assessed the duration of tests from the perspective of pathologists (7,8). Especially

Table 1. Patient characteristics

Variables	Entire cohort		
	Chip (n=34)	Control (n=31)	p-value
Age (year)	66.5 (62.5-71)	69 (64-73)	0.274
PSA (ng/dL)	7.27 (6.4-10.8)	7.5 (6-11)	0.768
PSA density (ng/mL)	0.16 (0.09-0.28)	0.13 (0.09-0.19)	0.105
Prostate volume (cc)	52 (36.5-72)	56 (36-75.8)	0.768

Data were expressed as median (interquartile range). Differences between patient groups assessed by Mann-Whitney U test and independent samples t-test. PSA: Prostate-specific antigen

Table 2. Comparison of chip and control group

Variables	Entire cohort		
	Chip (n=34)	Control (n=31)	p-value
Duration of pre-biopsy preparation (minute)	3.5 (3.2-3.7)	4.3 (3.5-5.8)	<0.001
Duration of biopsy procedure (minute)	4.25 (3.7-5.2)	3.96 (3.3-4.6)	<0.05
Duration of macroscopic examination (minute)	2.25 (1.5-2.2)	5.27 (4.5-6.1)	<0.001
Duration of sectioning (minute)	5.29 (3.5-7.9)	12 (10-12.4)	<0.001
Duration of embedding (minute)	2.2 (1.3-9.0)	11 (9.2-16.2)	<0.001
Duration of microscopic examination (minute)	12.29 (6.9-15.3)	15 (9.4-17.3)	0.143

Data were expressed as median (interquartile range). Bold values are statistically significant. Differences between patient groups assessed by Mann-Whitney U test and independent samples t-test

during the microscopic examination phase, it is significantly time-saving for the pathologist as BxChip™ allows 6 cores to be examined at the same time (Figure 3). Additionally, we wanted to evaluate the test time from the perspective of the urologists who conducted the biopsy. The chip arm demonstrated a statistically significant reduction in preparation time prior to biopsy. The observed time savings may be attributed to the increased efficiency in preparing two chip containers rather than twelve individual containers. However, the duration of biopsy procedures using the chip was notably extended in the experimental group. This observation may be ascribed to inserting the biopsy cores into the grooves requiring a period of learning and being comparatively more challenging than inserting them into the container.

Study Limitations

Although the study was designed prospectively, it was neither randomized nor blinded. Group allocation was based on chip availability, and due to the distinct specimen handling procedures, blinding of urologists and pathologists was

not feasible. Additionally, our study did not assess cost-effectiveness or sample quality. Some studies demonstrated that using a multiplex biopsy chips is quite cost-effective (7-9). Nevertheless, the utmost significance lies in the conservation of tissue integrity and length, as well as enhancing detection rates. In this context, multiple studies have shown the advantages of using a multiplex biopsy chip (7,8,10).

Conclusion

In this research, we examined the time difference between the standard prostate biopsy processing method and the BxChip™ approach, which enables the simultaneous processing of prostate biopsy specimens. Within the BxChip™ group, we observed a significant decrease in the duration needed, particularly when it came to the pathological assessment procedure. We consider the BxChip™ technique to be very useful in terms of time savings in clinical use, but larger-scale prospective randomized studies are needed in the future to assess cost-effectiveness, time saving, and sample quality.

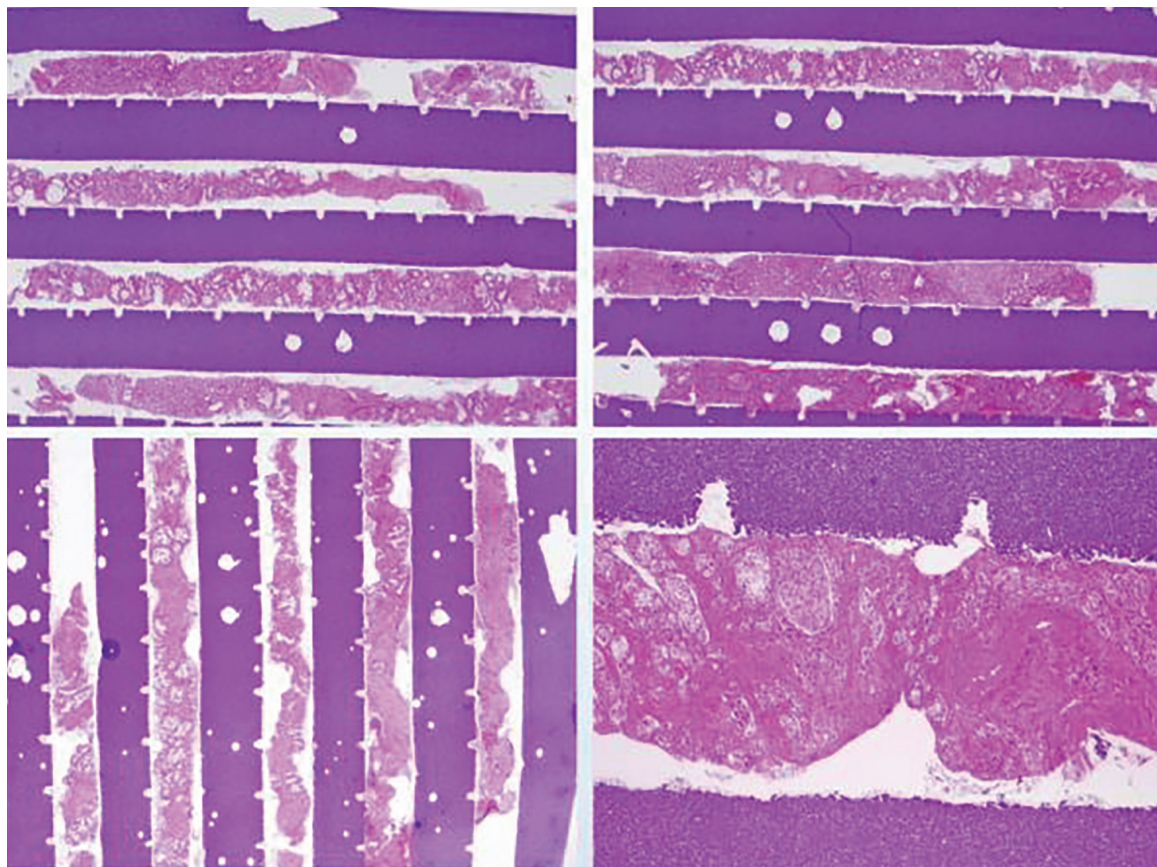


Figure 3. Microscopic examination of BxChip™

Ethics

Ethics Committee Approval: The study was conducted in accordance with the principles of the Declaration of Helsinki, after obtaining approval from the İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine Clinical Research Ethics Committee (IRB number: 83045809-604.01.02, date: 17.05.2019). detailed informed consent from all patients.

Informed Consent: Detailed informed consent from all patients.

Footnotes

Authorship Contributions

Surgical and Medical Practices: B.Ö., İ.G., Concept: B.Ö., İ.G., U.A., Design: B.Ö., İ.G., U.A., Data Collection or Processing: G.K., N.U., S.C., Analysis or Interpretation: U.A., G.K., Literature Search: S.Ç., B.E., Writing: U.A., G.K., İ.G., B.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

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