The SmartBx™- Initial experience with a semi-automated prostate biopsy core download system

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Introduction & objectives

The current handling of prostate biopsy cores has several limitations. Core fragmentation, loss of orientation, stacking, and adversely the core length,- are just few factors that may reduce cancer detection rate 1, or lead to data loss on the tumor location. The SmartBx™ system was developed to allow a semi-automated download of tissue cores from the biopsy needle onto a propriety designed cassette which integrates into the routine pathology lab processing. The core download in an oriented and straightened fashion is meant to address these above unresolved issues. Our objectives were to assess tissue core length and preservation, starting form biopsy core download throughout the full pathology lab process and it's effect on the Detection rate.

Materials & methods

The study was performed simultaneously in the Bnai Zion and the Haemek Medical centers. Tissue cores were taken with either a Pro-Mag gun or a Bard® Magnum Biopsy gun. Differences in core length and integrity were documented with an industrial camera. The core initial length was taken on the open needle (Figure 2). Cores were removed from the needle by either (1) Shaking into a formalin vial (standard), [2] By scraping the core onto a biopsy pad (sponge) and keeping it stretched between two pads throughout the pathology process[2-4], or [3] By using the SmartBx™ system. The core length and integrity was assessed following tissue processing (Sakura VIP-6), paraffin embedding and finally on the glass slide.

Results

<u>The experiments are on-going, mid term results are :</u>

Bnai Zion Medical center: Using the Standard method resulted in a tissue length reduction to 63.6% of the initial (n=56); while using the SmartBx method resulted in a tissue length reduction to 84.5% of the initial length(n=490) , a 33% increase in tissue yield (Figure 4) (P value<0.0.1). Core length in the standard method was 10.9 ±2.9 mm and 12±2.9 mm with the SmartBx (P value<0.0.1). Detection rate results of patients with PSA<10 who went through 12 core biopsy procedure performed completely with one of the methods (Smartbx/Standard) were compared. For standard method detection rate was 30.8% (n=26; PSA=5.2±2.65). Using the SmartBx , Detection rate was 37.8% (n=29; PSA= 5.5±2).

Haemek Medical Center Using the Standard method resulted in length reduction to 59.2% of the initial (n=191); Using the biopsy pads resulted in tissue sparing of 66.2% (n=157) and using the SmartBx method resulted in a tissue sparing of 78.4% (n=212) , Increase of 32.5% in yield between the SmartBx and standard method (P value<0.0.1) (Figure 5). Core length was 9.3±4.3, 10.1±3.3 and 11.8±4.7 mm using the standard method, the biopsy pad (sponge) or the SmartBx (correspondingly) (P value<0.0.1). In this experiment for each patient , the biopsy cores were divided between the three methods evenly. Detection rate per core was measured to be 11.5 %(n=715); 11.8 %(n-288) and 13.8 %(n-530) for standard methods, biopsy pad and SmartBx , respectively.

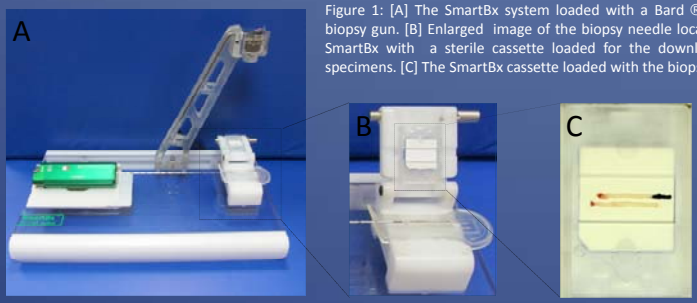

Figure 1: [A] The SmartBx system loaded with a Bard ® Magnum biopsy gun. [B] Enlarged image of the biopsy needle located on the SmartBx with a sterile cassette loaded for the download of the specimens. [C] The SmartBx cassette loaded with the biopsy cores.

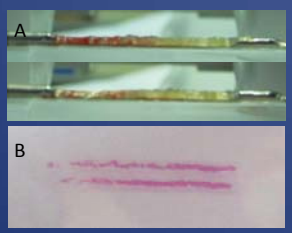

Figure 2: [A] The biopsy cores were documented on the biopsy gun needle as the baseline for the core length. [B] biopsy sections on the slide were documented and compared to the core length documented on the needle.

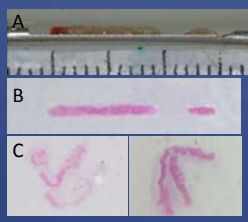

Figure 3: Using the SmartBx, all biopsy fragment are kept in their original location along the needle notch through processing to histology slide [A,B]. [C] Using the standard method , Small fragments may be lost during processing and embedding,. Entangled cores can cause to a smaller tissue area analyzed by the pathologist.

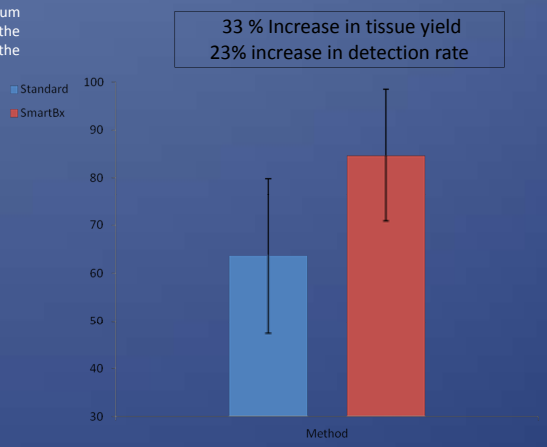

Figure 4: Biopsy tissue yield with the SmartBx compared to standard method .

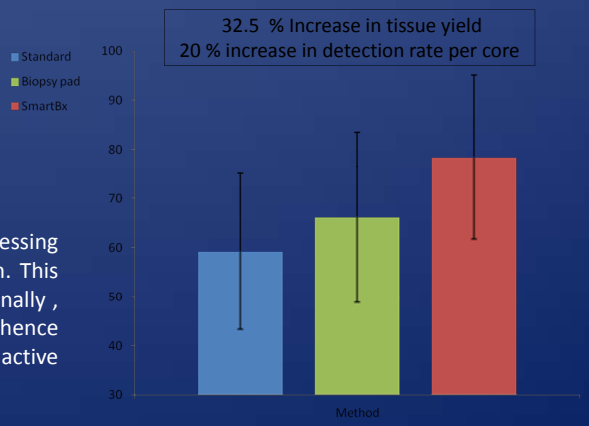

Figure 5: Biopsy tissue yield with the SmartBx compared to standard method and biopsy pad.

Conclusions

The initial experience of tissue needle biopsy cores download and processing seems promising as tissue cores kept their integrity, length and orientation. This may reflect on clinical yield as well as on time and ease of the procedure. Finally , these initial results demonstrates a 20% increase in cancer detection rate , hence this system has the potential to significantly impact the future detection, active surveillance and treatment of prostate cancer.

[1] Obek et al, J. Urol. 187, June 2012. [2] Benedetto et al. Prostate cancer, Volume 2011.
[3] Stock et al. JOURNAL OF ENDOUROLOGY, Volume 22, Number 6, June 2008 [4] Rogatsch et al. Hum Pathol. 2000 Sep;31(9):1102-7.