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Smartglass augmented reality-assisted targeted prostate biopsy using cognitive point-of-care fusion technology

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Abstract

Introduction: MRI-guided targeted biopsy has become standard of care for diagnosis of prostate cancer, with establishment of several biopsy techniques and platforms. Augmented reality smart glasses have emerged as novel technology to support image-guided interventions. We aimed to investigate its usage while prostate biopsy.

Methods: MRI with PIRADS-lesions ≥3 was uploaded to smart glasses (Vuzix Blade^{R}) and augmented reality smart glasses-assisted targeted biopsy (SMART-TB) of the prostate was performed using cognitive fusion technology at the point of care. Detection rates were compared to systematic biopsy. Feasibility for SMART-TB was assessed (10 domains from bad [1] to excellent [10]).

Results: SMART-TB was performed for four patients. Prostate cancer detection was more likely for SMART-TB (46%; 13/28) than for systematic biopsy (27%; 13/48). Feasibility scores were high [8–10] for practicality, multitasking, execution speed, comfort and device weight and low [1–4] for handling, battery and image quality. Median execution time: 28 min; Investment cost smart glass: 1017 USD.

Conclusion: First description of SMART-TB demonstrated convenient feasibility. This novel technology might enhance diagnosis of prostate cancer in future.

KEYWORDS
augmented reality, prostate biopsy, prostate cancer, smart glasses, Vuzix Blade

1 | INTRODUCTION

Multiparametric magnetic resonance imaging (mpMRI) of the prostate has been a game changer for the diagnosis of prostate cancer (PCA) for almost a decade. However, despite the doubtless benefits of mpMRI in the detection of PCA, there is still ongoing discourse on how best to perform targeted biopsy.[1,2] Techniques for targeted prostate biopsy include in-bore MRI biopsy, software fusion biopsy and cognitive fusion biopsy, among others, which have comparable detection rates for PCA.[3] To improve the precision of prostate

biopsy, novel technologies like high-resolution microultrasound have been implemented to supplement the diagnostic armamentarium of visualisation techniques.[4]

Virtual and augmented reality applications are currently facilitating the real-time integration of preoperative imaging into surgical procedures.[5] One technical application is the use of smart glasses, consisting of a head-mounted display with a see-through display for augmented reality-assisted surgery. We have previously reported on the feasibility, safety and usefulness of augmented reality smart glasses in urological surgery.[6] Regarding prostate biopsy, virtual reality with smart glasses has previously been used for patient counselling.[7] However, the use of augmented reality to assist prostate biopsy has not yet been reported.

Here, we report for the first time the use of augmented reality in prostate biopsy through augmented reality smart glasses-assisted targeted biopsy (SMART TB) of the prostate, using cognitive point-of-care fusion technology. We quantified the feasibility of this novel technology for 10 domains. As smart glasses might offer a cost-effective alternative to the abovementioned hardware systems for assisting targeted prostate biopsy, we also assessed operating room times and investment costs for SMART TB.

2 | METHODS

We prospectively included four patients in this pilot proof-of-concept study for SMART TB. The study was approved by the local ethics board (2020-15290). To avoid unnecessary biopsy in asymptomatic men with moderate PSA elevation from 2 to 10 ng/ml, we performed preoperative imaging according to the EAU guidelines.[8] Therefore, every patient underwent preoperative mpMRI of the prostate with confirmed detection of at least one suspect prostate lesion. A maximum of two targets for biopsy were labelled for each patient. All initial MRI scans were performed using 1.5- and 3-T MRI scanners. All mpMRIs were reviewed and analysed by a genitourinary expert from the department of radiology, and all external imaging was subjected to quality checks. T2-weighted, contrast-enhanced, and diffusion-weighted series were reproduced. MRI lesions were given a Prostate Imaging Reporting and Data System (PI-RADSv2) score from 1 to 5 to stratify their risk of PCA.[9]

The mpMRI scans were processed to produce a two-dimensional image copy including the standardised mpMRI reporting scheme with the labelled PIRADS index lesion and a copy of the axial T2-weighted image of the base/mid/apex with demonstrative landmarks and the labelled target lesion/lesions. Prior to biopsy, these data were uploaded to the Vuzix Blade^{R} smart glasses (version 1.0; Figure 1) as a JPEG file via micro-USB 2.0. The Vuzix Blade^{R} smart glasses generate an augmented reality view and can be used wirelessly and independent of any other device. As it has a head-mounted display, the information is projected through a see-through technique in front of the user's eye. Navigation is manually possible via the touchpad or through voice control. The smart glasses feature a 10-degree field of view, 64 GB memory, 8 MP HD camera for 1080 p video, head motion tracking system, micro-SD slot and battery power (rechargeable) of 2 h, and it is compatible with both iOS and Android.[10]

According to the EAU guidelines, targeted biopsy of the prostate is recommended for lesions with PIRADS scores between 3 and 5.[8] Because of this, we performed an ultrasound-guided transrectal approach (HiVision Ascendus, Hitachi Medical Systems^{R}) after perioperative application of intravenous antibiotics (ceftriaxon 2 g or ciprofloxacin 400 mg) and rectal disinfection with povidone-iodine. To improve patient tolerance, infiltration with local anaesthesia (mecain 2%) was administered to the periprostatic plexus before beginning the regular biopsy. In the meantime, while the patient was sitting in the "biopsy position", we retrieved the previously uploaded mpMRI files through augmented reality with the head-mounted see-through Vuzix Blade^{R} (Figure 1). Navigation of the Vuzix Blade^{R} was possible through voice commands under aseptic conditions or manually via a touchpad. Target biopsy was then performed by a single experienced surgeon with a fusion biopsy case load of more than 150 cases using the Hi-RVS Preirus-System (HITACHI^{R}), which was always followed by a systematic transrectal 12-core biopsy. Standard transrectal ultrasonography-guided biopsy obtained cores from the peripheral zone of the prostate at the base, mid-gland and apex. In total, we retrieved a minimum of 18 and maximum of 20 samples per patient (target biopsy, range 4–8 cores; systematic biopsy, 12 cores), always starting with the target biopsy. The number of cores taken was related to the lesion count and lesion size, and it depended on the surgeon's assessment. During the target biopsy, the surgeon cognitively matched the real-time transrectal ultrasound with the mpMRI images that had been previously uploaded to the Vuzix Blade^{R} smart glasses. To optimise accuracy, the surgeon adjusted the angle of the hand-guided puncture line according to specific landmarks seen on the corresponding mpMRI images displayed in front of their eyes. The surgery field was unobstructed, and cognitive matching between MRI images and ultrasound was possible through view-switching to display the virtual screen in the upper right field of vision.

2.1 | Data acquisition

Each core was separately enumerated and processed for examination by our local uropathologist expert. The feasibility of SMART TB was assessed by the performing surgeon according to the following criteria (1 = bad to 10 = excellent) adopted by Galati et al. for 10 domains: execution speed, physical stress, comfort, surgery improveness, multitasking, practicality, image quality, battery autonomy, device handling, and device weight.[11] Clinical data were collected in a dedicated database. Intraoperative variables, postoperative complications and outcomes were assessed. Descriptive statistics were used to report patient data.

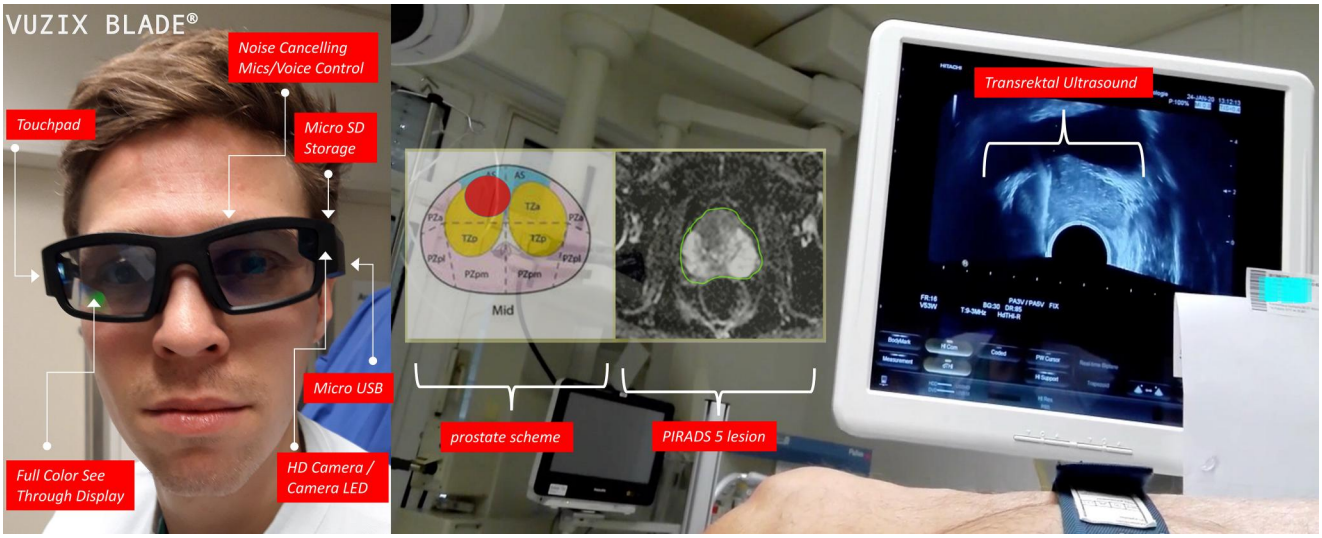

FIGURE 1 Modified illustration of usage of the Vuzix Blade[R] and transrectal ultrasound (HiVision Ascendus[R], Hitachi Medical Systems) for augmented reality smart glasses-assisted targeted biopsy. Surgeon wearing smart glasses (left side) and reconstructed surgeon's perspective through the Vuzix Blade[R] while performing the biopsy, showing the simultaneous view of the transrectal ultrasound and mpMRI at the point of care (right side)

3 | RESULTS

Smart glasses-assisted targeted biopsy of the prostate was performed in four patients (patients A–D) after previous elucidation. All patients had suspected PCA and were undergoing biopsy for the first (n = 3) or second (n = 1) time. The average age of the four male patients was 66.25 years. Patients presented a mean PSA elevation of 6.6 ng/dl, and a suspicious digital rectal examination (DRE) was obtained in one patient (Table 1).

We detected PCA in all four patients, while clinically significant prostate cancer (csPCa) was detected through SMART TB and systematic biopsy in 50% of patients in the study. Overall, 76 cores were obtained, and 26 (34%) of these showed PCA of any Gleason score (≥6). Detailed core analyses demonstrated superior detection rates for SMART TB over systematic biopsy. 13 of 28 cores (46.42%) for SMART TB and 13 of 48 cores (27.1%) for systematic biopsy revealed PCA. Considering the PI-RADS v2 score, PIRADS lesions (n = 7) were distributed over the entire prostate, but they were primarily found in the apex (57.1%) and in the peripheral zone (85.71%) independent of their axial level. The detection rates for particular PIRADS lesions showed 0% PIRADS 3 (1/7), 80% PIRADS 4 (2/7) and 31.25% PIRADS 5 (4/7). The distribution of positive lesions and their location are listed in Table 2. Histological examination revealed adenocarcinoma of the prostate in all cases (100%), with a maximum Gleason score of 6 for two patients (A and D) and a Gleason-score of 7a for two patients (B and C). Positive cores for prostate cancer were observed to be more frequent in SMART TB then for systematic biopsy (46.42% vs. 27.1%) while using less biopsies (28 vs. 48; Table 2). We observed positive cores for systematic biopsy versus SMART TB (%) in patient A (58.3 vs. 83.3), patient B (8.3 vs. 50.0), patient C (25.0 vs. 25.0) and patient D (16.6 vs. 37.5). While patient A underwent curative radiation, patients B and C were treated with radical prostatovesiculectomy. Patient D was lost to follow-up.

TABLE 1 Patient pre-interventional details

Patient factors		
Parameter, unit		
Median age (years)	66.25	(range 61–77)
ECOG 0	75%	
ECOG 2	25%	
iPSA (ng/ml)	6.6	(range 4.1–8.9)
PSA ratio	0.23	(range 0.16–0.35)
PSA density (ng/ml^2)	0.10	(range 0.08–0.11)
Prostate volume (ml)	67.5	(range 37–110)
Suspicious DRE, n (%)	1	(25%)
Previous negative biopsy, n (%)	1	(25%)
Total PIRADS lesions, n (%)	7	
PIRADS 3	1	(14.3%)
PIRADS 4	2	(28.6%)
PIRADS 5	4	(57.1%)
Localisation PIRADS lesion, n (%)		
Apex PZ	4	(57.1%)
Mid	1	(14.3%)
Base	2	(28.6%)

The performing surgeon assessed the new configurated SMART TB procedure based on the abovementioned criteria and gave the following scores (scale from 1 to 10): execution speed [8] physical

TABLE 2 Patient post-interventional details

Results of biopsy		
Overall positive cores, *n* (total cores)	26	(76)
Positive cores, %	34%	
Positive cores systematic biopsy, *n* (total cores)	13	(48)
Positive cores systematic biopsy, %	27.1%	(range 8.33–58.33)
Positive cores SMART TB, *n* (total cores)	13	(28)
Positive cores SMART TB, %	46.42%	(range 25–83.3)
Positive cores per PIRADS lesion, *n* (%)		
PIRADS 3, % (location)	1	(0%)
PIRADS 3 (patient B)	0%	(apex PZpm left)
PIRADS 4, % (location)	2	(80%)
PIRADS 4 (patient A)	83.3%	(apex PZpl right)
PIRADS 4 (patient B)	75%	(base AS left)
PIRADS 5, % (location)	4	(31.25%)
PIRADS 5 (patient C)	0%	(mid PZa left)
PIRADS 5 (patient C)	50%	(base PZpl left)
PIRADS 5 (patient D)	25%	(apex PZpl right)
PIRADS 5 (patient D)	50%	(apex PZpm right)
Intraoperative adverse events (EAUiaiC)	None	
postoperative complications within 7 days (Clavien Dindo >1)	None	
Histological results		
Positive cores for systematic biopsy versus SMART TB, %		
Patient A	58.3 versus 83.3%	
Patient B	8.3 versus 50.0%	
Patient C	25.0 versus 25.0%	
Patient D	16.6 versus 37.5%	
Prostate cancer, *n* (%)	4	(100%)
Patient A	Gleason 6	
Patient B	Gleason 3 + 4	
Patient C	Gleason 3 + 4	
Patient D	Gleason 6	
csPCa (Gleason $\geq$ 3 + 4), *n* (%)	2	(50%)
Follow up (1 year), *n*		
Radical prostatectomy	2	
Curative radiation	1	
Lost of follow up	1	

Abbreviation: SMART TB, smart glasses-assisted targeted biopsy.

stress [5] comfort [8] surgery improvement [5] multitasking [10] practicality [10] image quality [3] battery autonomy [4] device handling [4] and device weight [8] (Figure 2). According to EAUiaiC and Clavien Dindo classifications, there were no intraoperative complications and only minor postoperative complications. The postoperative complications included haematuria, perineal pain and spermaturia, but they did not exceed a Clavien Dindo score of >1 within 7 days of the intervention.

The median operating room time was defined as the time from the beginning of the transrectal ultrasound until placement of the

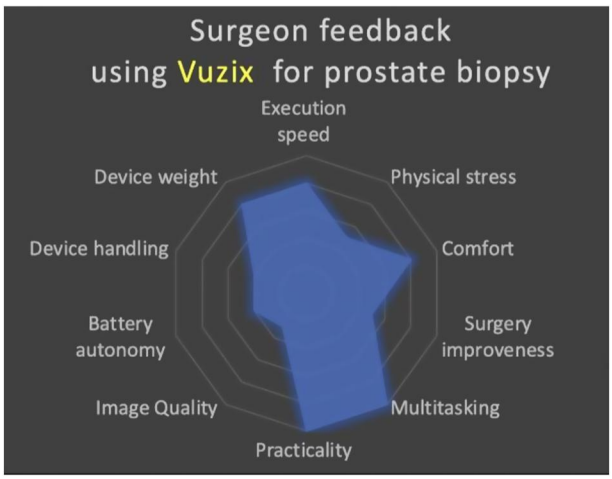

FIGURE 2 Surgeon's assessment of the use of Vuzix Blade[R] for prostate biopsy (SMART TB)

rectal tamponade at the end of the prostate biopsy. The median OR time was 28 min for four cases. Cost analyses showed that, besides the general cost of the prostate MRI and biopsy equipment, the investment cost for the Vuzix Blade[R] smart glasses is 1017 USD.

4 | DISCUSSION

The use of augmented reality smart glasses has been demonstrated to optimise surgical understanding; however, even though the feasibility, safety and usefulness of smart glasses during urological surgery have been investigated,[6,12] technical maturity of these devices are yet missing.[13] Therefore, we performed a pilot proof-of-concept study on the benefits of smart glasses for cognitive targeted biopsy of the prostate under support of augmented reality (SMART TB) for intraoperative access to mpMRI imaging of the prostate. SMART TB was performed in four patients, and the post-intervention data obtained using this technology were compared to simultaneously executed 12-core systematic biopsy and to existing biopsy techniques.

Smart glasses-assisted targeted biopsy was associated with a more likely detection then the 12-core systematic biopsy (46.42% vs. 27.1%) for PCA of any kind while SMART TB needed less biopsy cores then systematic biopsy ($n = 28$ vs. 48) for detection of prostate cancer. Further histological examination revealed adenocarcinoma of the prostate in all patients, with csPCa detection in half of the cases (50%). For regular cognitive MRI-guided biopsy techniques without smart glasses, the literature reports detection rates between 27% and 69.7% for csPCa.[14–17] A multicentre randomised controlled trial by Wegelin et al. including 665 men showed no significant differences in the detection rates of csPCa among three different MRI-based target biopsy techniques,[3] in-bore MRI target biopsy (MRI-TB), MRI-TRUS fusion target biopsy (FUS-TB) and cognitive registration target biopsy (COG-TB), which showed detection rates of 55%, 49% and 44%, respectively.[3] Besides its complex and expensive set-up, there is evidence that MRI-TB achieves superior detection rates compared to FUS-TB and COG-TB[18]; however, this is an ongoing debate. While Drost et al. stated that the MRI pathway generally has better diagnostic accuracy for csPCa compared to systematic biopsy,[2] Rouviere et al. demonstrated improved detection rates by combining both techniques, with substantial added value.[19] These previous studies reported poorer detection rates for targeted biopsy over systematic biopsy (32.3% vs. 29.9%)[19] than that reported in the current study (46.42% vs. 27.1% for SMART TB vs. systematic biopsy). Regarding the PI-RADSv2 score classification, we performed target biopsies for a total of seven PIRADS index lesions, which were primarily located in the peripheral zone (85.71%) of the prostate. Detection rates in terms of PIRADS scoring were 0%, 80% and 31.25% for PIRADS 3, PIRADS 4 and PIRADS 5 lesions, respectively. The data in the literature is highly heterogeneous,[20] with detection rates of csPCa after target biopsy of 6% for PIRADS 1/2, 12% for PIRADS 3, 48% for PIRADS 4 and 72% for PIRADS 5.[21] Barkovich et al. stated that PI-RADSv2 has good overall sensitivity for suspected lesions with a PIRADS score ≥3.[21] Comparison with these findings is not possible due to the small cohort size of our study ($n = 4$), but this should be considered in future studies.

Some minor findings also need to be discussed. Numerous three-dimensional visualisation techniques have been investigated in the fields of prostate biopsy[22] and surgery, especially in terms of education, training, surgical planning and intraoperative guidance.[23] However, according to Wang et al., promising evidence that these applications will be useful for prostate procedures, aside from determining the clinical utility and validating the technologies, is still missing.[13,23] Our findings demonstrate good overall operability for SMART TB. According to Galati et al., assessment of SMART TB with the smart glasses by our surgeon according to the abovementioned criteria (Figure 2) revealed good clinical practice in the domains of practicality, multitasking, execution and comfort, while surgery improvement (due to battery autonomy), device handling and image quality of the mpMRI of the prostate require improvement. Visual fatigue caused by the use of similar head-mounted displays has been reported by Hirota et al. for virtual reality and two-dimensional displays[24] was not present in our study what may refers to brief period of wearing the smart glass while execution. However, even with the low image quality of the virtual see-through display (Vuzix Blade[R], version 1.0), cognitive matching of real-time transrectal ultrasound and mpMRI images at the point of care optimises orientation and navigation, especially when multiple PIRADS lesions are present in the same patient. However, the major advantage for SMART TB over regular COG-TB is cognitive matching at the point of care of real-time transrectal ultrasound and mpMRI images under aseptic conditions what optimises orientation and navigation, especially when multiple PIRADS lesions are present in the same patient. In contrary a major disadvantage is yet low image quality of the virtual see-through display compared to common computer image resolution and even if of its very slight construction the Vuzix Blade[R] delimits the field of vision. With future advancements in the technology, especially enhanced image quality, it can be assumed that the

optimised intraoperative guidance provided by augmented reality will also lead to higher accuracy. Our results are in line with the statements of other authors that technological improvements are required before these devices can be used for standard procedures in operating rooms,[11] and more studies are needed to justify their widespread use.[23]

To the best of our knowledge, this is the first pilot proof-of-concept study to evaluate the benefits of PCA detection using augmented reality smart glasses to assist in targeted biopsy of the prostate. Detection of csPCa was found by both procedures SMART TB and systematic biopsy, but even was more likely when SMART TB was performed. In addition SMART TB needed less biopsy cores then systematic biopsy for detection of prostate cancer. Compared to regular cognitive MRI-guided biopsy techniques, we found no major difference in detection rates. In addition, SMART TB was, as expected, safe for both surgeons and patients, with no intraoperative complications (EAUiaiC) and no major postoperative adverse events (Clavien Dindo). With improvements in the see-through display to optimise the image quality, this technique is expected to be widely implemented in clinical practice.

Our study has some limitations. In general, SMART TB stays a cognitive target biopsy. Therefore, the same detection rates may have been achieved with regular COG-TB, or even better detection rates with FUS-TB or MRI-TB, without the support provided by smart glasses. In addition, detection rates obtained using SMART TB are highly dependent on the experience of the executing surgeons and their ability to read and understand mpMRI and ultrasound of the prostate,[25,26] beside the fact that the prostate scheme should be reproducible for any urologist. These findings have previously been reported for COG-TB and, interestingly, also for FUS-TB. Mager et al. declared that a minimum of ~60 MRI target biopsies should be performed for a surgeon to be confident with the procedure.[27] Although we considered this benchmark, measuring individual knowledge and experience is difficult. In addition we have to declare that the same surgeon was executing systematic biopsy as well SMART TB and therefore he was not blinded to the results of mpMRI what may leads to discrepancy. Finally, our study had a small cohort size and SMART TB as well assessment of SMART TB was performed by a single surgeon, which for sure represents a source of bias.

Finally, MRI target biopsy of the prostate increases detection rates independent of the specific technique.[26] Due to the enormous heterogeneity in data reporting, there is no clear recommendation for a specific biopsy method. COG-TB is fast, simple, and requires no additional expensive hardware.[26] Therefore, MRI-guided biopsy may become the standard method for any kind of prostate biopsy, whereas COG-TB may be principally indicated for large PIRADS index lesions.[26] Therefore, we aim to improve COG-TB through augmented reality using smart glasses. Further studies using new-generation smart glasses with optimised image quality are needed, considering possible virtual three-dimensional visualisation of individual prostate models to investigate the benefits of SMART TB. This technology has the potential to increase the detection rates of csPCa, in addition to other benefits such as convenient handling and reduced costs.

5 | CONCLUSION

First description of our pilot proof-of-concept study demonstrated convenient feasibility for SMART TB. We believe to have created a feasible and generalisable technique that should be compared to other techniques in prospective studies. This time- and cost-effective novel technology might enhance the application of MRI-guided targeted prostate biopsy in the future, even if further investigation with comparison to well-established biopsy techniques are still needed.

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None.

CONFLICT OF INTEREST

None declared.

AUTHOR CONTRIBUTIONS

Peter Sparwasser: design, execution, manuscript writing, conceptualisation. Maximilian Haack: data analysis, investigation, execution, editing. Stefan Epple: data analysis, investigation, execution. Steffen Zeymer: execution. Lisa Frey: data analysis, investigation. Robert Dotzauer: supervision, critical revision, interpretation of data. Florian Jungmann: resources, assessment and editing of imaging. Katharina Boehm: conceptualisation, critical revision. Thomas Hoefner: supervision, critical revision, project administration. Igor Tsaur: supervision, critical revision, project administration. Axel Haferkamp: supervision, critical revision. Hendrik Borgmann: design, manuscript writing, conceptualisation, methodology.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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