




# Aquablation of the prostate: single-center results of a non-selected, consecutive patient cohort

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## Abstract

**Purpose** Aquablation of the prostate using the AquaBeam™ system promises equivalent functional outcomes, reduced learning curve, and improved sexual function compared to transurethral prostate resection as shown in prospective randomized trials. This prospective cohort study aims to evaluate if published results can be transferred into the clinical routine in a non-selected patient collective.

**Methods** This study includes all patients treated between September 2017 and June 2018 with Aquablation of the prostate. Patients have been evaluated prospectively for the perioperative course and early follow-up. Besides voiding parameter and symptom score, TRUS-volume change, ejaculatory function, and adverse events have been recorded.

**Results** 118 consecutive patients have been treated in the given time. Aquablation could be carried out successfully in all patients. IPSS, QoL, Qmax, and PVR improved significantly after the procedure and continued to improve during 3-month follow-up. Mean OR time was 20 min, TRUS volume decreased by 65%, and 73% of the patients retained antegrade ejaculation. Thirteen adverse events (> Clavien-Dindo I) occurred in 10 patients.

**Conclusion** The surgical ablation of the prostate using Aquablation achieved significant and immediate improvement of functional voiding parameters Qmax and PVR as well as symptomatic improvement of IPSS and QoL. Aquablation seems to be safe and effective with a low perioperative complication profile even in a non-selected group of patients.

**Keywords** BPH · BPO · Aquablation · AquaBeam · Waterjet

## Introduction

The technological developments of recent years introduced new methods into the surgical treatment of the benign prostatic hyperplasia (BPH). Transurethral endoscopic enucleation of the prostate—utilizing various energy sources—and transurethral vaporization techniques have been introduced

and added into the treatment algorithms for LUTS due to benign prostatic obstruction (BPO) [1–4]. Most recently, Aquablation of the prostate using the AquaBeam™ system, exploiting the power of a high-velocity waterjet, offers a new, innovative and minimally invasive alternative for men suffering from BPO [5–7].

Hydro-jet dissection plays a significant part in the surgery used in many surgical specializations. Tumor enucleation surgeries in liver, bone, brain, kidneys and lungs provided hopeful results [8–11]. Since 2011, hydro-jet dissection has been used for the treatment of bladder tumors [12, 13] and Aquablation treatment for BPO was first described in man in 2013 [14], with the unique feature, that in Aquablation, the tissue removal is automated by a waterjet that is robotically executed based upon surgeon planning. The procedure is carried out and controlled under real-time transrectal ultrasound.

A growing number of publications supports the efficacy of Aquablation in terms of IPSS- and QoL-improvement as

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well as in terms of improvement of maximum urinary flow rate ( $Q_{max}$ ) and post void residual urine (PVR) [14–17].

The WATER study, a double-blind, prospective, randomized multicentre clinical trial, compared Aquablation of the prostate with the transurethral prostate resection. Aquablation achieved similar functional outcomes but with a lower risk of sexual dysfunction and reduced morbidity [17]. A pre-specified analysis showed that a surgical resection using Aquablation in large prostates (50–80 g) led to a higher symptom score decrease as well as a decreased rate of postoperative complications as compared to TUR-P [16].

Despite the published results from well-designed randomized controlled trials (RCT), large-scale data from an unselected patient cohort are yet missing. We report the so far largest, prospective single-center experience of non-selected patients treated with Aquablation.

## Methods

All patients treated with Aquablation due to symptomatic BPO between September 2017 and June 2018 in our institution (Dept. of Urology, AK Harburg, Hamburg, Germany) have been included into this prospective cohort study. The only exclusion criterion was anticoagulation therapy other than Aspirin 100 mg. No other in- or exclusion criteria have been defined to ensure “real-life” criteria. Patients underwent standard preoperative workup. Maximum urinary flow rate ( $Q_{max}$ ) and post-voiding residual urine (PVR), international prostate symptom score (IPSS) and IPSS-Quality of life measurement (QoL) were recorded preoperatively, at the day of discharge and after 3 months. Ultrasound including transrectal prostate volume assessment as well as post-void residual urine (PVR) and PSA were assessed preoperatively and after 3 months. Hemoglobin was measured preoperatively and on postoperative day 1. The postoperative course, the occurrence of adverse events as well as time to catheter removal were recorded. The baseline characteristics are shown in Table 1.

The AquaBeam™ (PROCEPT BioRobotics, Redwood Shores, CA, USA) system was used for the surgical Aquablation of the prostate (Fig. 1). If no contraindications were present, patients received tranexamic acid (15 mg/kg body weight) 30 min prior to the procedure. The procedure was carried out using perioperative antibiotic prophylaxis, according to the local resistance profile. The patient was placed in the dorsal lithotomy position. With real-time prostate visualization using a BK Ultrasound bi-plane transrectal ultrasound (BK Medical, Peabody, MA, USA) and cystoscope, the surgeon uses the AquaBeam Conformal Planning Unit (CPU) to mark the target resection contour. Under the surgeon’s control, the ablation of tissue is robotically executed using a high-velocity waterjet to resect adenomatous

**Table 1** Patients characteristics

Characteristic	Mean (SD, range)
Age	69 (8, 88–52)
Prostate volume (ml)	64.3 (32, 20–154)
PSA	4.3 (4.67, 0.18–36.3)
IPSS	21.09 (6.85, 7–35)
QoL score	4.56 (1.27, 0–6)
Q max. (ml/min)	10.75 (5.84, 2.3–40)
PVR (ml)	158.9 (282.9, 100–2500)
Hemoglobin (mg/dl)	14.2 (1.52, 9.2–17.6)
Procedure time (min)	20 (7.91, 9–53)
Aquablation time (min)	3.2 (1.22, 1.48–7.31)
Time to catheter removal (days)	2.2 (0.46, 2–4)

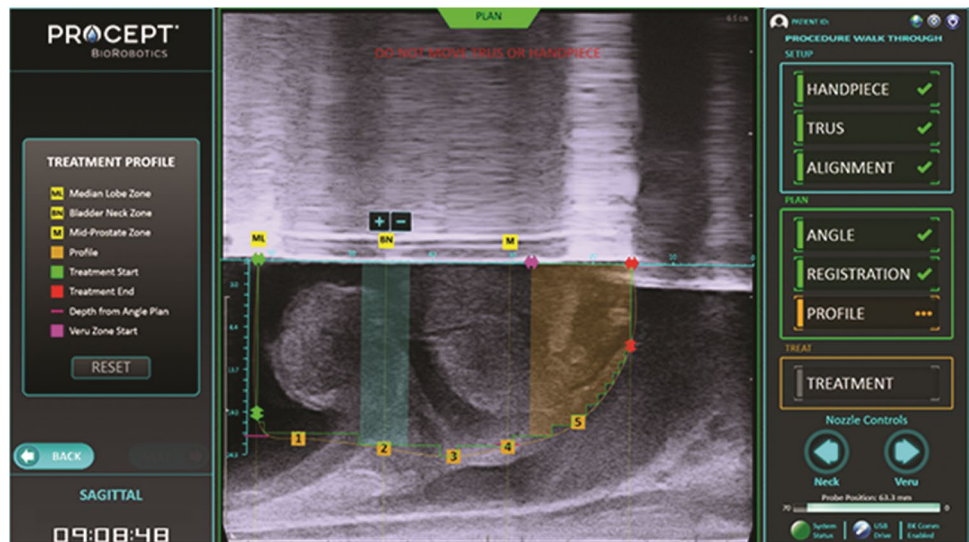
IPSS International prostate symptom score, QoL score Quality of life score, Q max maximum urinary flow, PVR post-voiding residual urine



**Fig. 1** AquaBeam system (PROCEPT BioRobotics, Redwood Shores, CA, USA) including high pressure pump and planning unit

tissue while avoiding the verumontanum and ejaculatory ducts. Using the ultrasound image of the prostate, treatment length, sweep angle and depth of treatment can be adjusted and the anatomical structures responsible for continence and ejaculatory function can be spared out (Fig. 2). After finalizing the planning phase, the heat-free, high-velocity waterjet is applied. Penetration depth, as well as the rotational and longitudinal movement of the water-jet nozzle along the previously marked resection area, is calculated by the AquaBeam™ System and completely robot controlled to ensure precise and fast removal of the prostatic tissue. After

**Fig. 2** Sagittal planning view prior to Aquablation (with permission of PROCEPT Biorobotics, Redwood Shores, CA, USA). Green line: treatment contour; Green zone: Bladder neck area; Orange zone: Veru cut area; Red arrow: Treatment end



**Fig. 3** Catheter tensioning device (CTD, PROCEPT Biorobotics, Redwood Shores, CA, USA). Ensures bladder neck traction, also in moving patients

the procedure, a three-way Foley catheter is inserted, and bladder irrigation is commenced. Bladder neck traction is applied for the first hours after the procedure. The placement of the so-called catheter-tensioning device, CTD, (PROCEPT BioRobotics, Redwood Shores, CA, USA) (Fig. 3) helps for consistent balloon traction. The transurethral catheter was removed depending on the color of the urine.

## Statistical analysis

Statistical analysis was carried out using Minitab 17 software. As indicated, the t-paired test was used. Statistical significance was accepted at  $p$  value  $< 0.05$ .

## Results

One hundred and eighteen consecutive patients have been included into this prospective cohort study. Baseline characteristics are summarized in Table 1. No patient had previous BPH surgery or treatment of urinary stricture or prostate cancer in the reported collective. Mean age was  $69 \pm 8$  (range 52–88) with a prostate volume

from  $64.3 \pm 32$  ml (range 20–154 ml) and baseline IPSS  $21.09 \pm 6.85$  (range 7–35) such as QoL score  $4.56 \pm 1.27$  (range 0–6) points. Maximum urinary flow (Qmax) was  $10.75 \pm 5.84$  (range 2.3–40) ml/s, while post-voiding residual urine (PVR) ranged prior the procedure from 100 to 2500 ml with a mean amount of  $158.9 \pm 282.9$  ml. Prior to surgery, 29 patients (24.6%) required either a transurethral or suprapubic catheter due to recurrent urinary retention. Mean PSA was  $4.3 \pm 4.67$  (range 0.18–36.3)  $\mu\text{g/L}$ .

Aquablation was carried out successfully in all patients. Mean operative time, defined as the time from TRUS placement until the final urinary catheter placement, was  $20 \pm 7.91$  (range 9–53) min. As an expression of the learning curve, the mean OR time in cases 1–50 was 24.2 min and dropped to a mean OR time of 17 min after this. Functional outcome and morbidity were comparable, in any case. The mean Aquablation time measured  $3.2 \pm 1.22$  (range 1.48–7.31) min only. 9 patients needed two passes of the waterjet, one patient three passes, with increasing need for multiple passes with a prostate volume above 120 cc. The transurethral catheter time was  $2.2 \pm 0.46$  (range 2–4) days. At discharge, 112 patients (95%) proved sufficient voiding and have been discharged without catheter. 3 out of the 6 patients, that have been discharged with catheter suffered from recurrent retention prior to surgery. The catheter has been removed successfully in all six patients during follow-up.

Intraoperative electrocautery was used in four patients (3.4%), proving that Aquablation could be carried out completely athermal in over 96% of the cases.

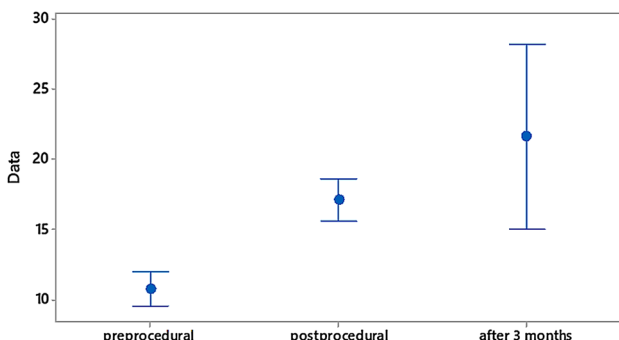
Hemoglobin levels dropped from a mean of  $14.2 \pm 1.52$  (range 9.2–17.6) g/dl at baseline to  $12.42 \pm 1.67$  (range 7.2–16.2,  $p < 0.001$ ) g/dl postoperatively, with three patients (2.5%) requiring blood transfusion.

Thirteen relevant perioperative adverse events occurred in overall in 10 (8.5%) patients. Nine events were categorized

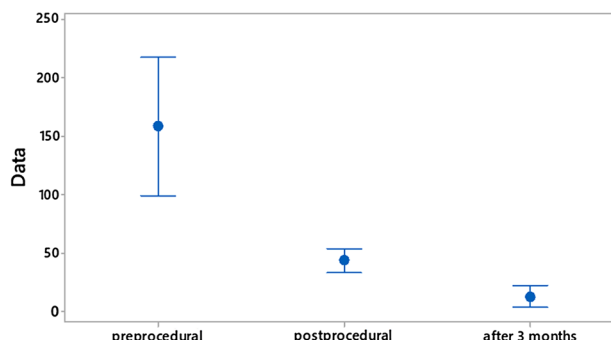
**Table 2** Functional outcomes

Characteristic	Preoperative	Postoperative	Follow-up (after 3 months)
<b>IPSS</b>			
Mean (SD, range)	21.09 (6.85, 7–35)	10.27 (6.74, 0–30)	7.25 (5.2, 0–20)
95% CI		(–11.989; –8.540)	(–16.63; –10.31)
<i>P</i> value		<0.001	<0.001
<b>Qol score</b>			
Mean (SD, range)	4.56 (1.27, 0–6)	2.25 (1.13, 0–5)	1.52 (1.26, 0–4)
95% CI		(–2.634; –1.985)	(–3520; –2420)
<i>P</i> value		<0.001	<0.001
<b>Q max. (ml/min)</b>			
Mean (SD, range)	10.75 (5.84, 2.3–40)	17.1 (7.838, 4.4, 42.6)	21.62 (12.77, 5.6–53.7)
95% CI		(4752; 8564)	(2.09; 18.35)
<i>P</i> value		<0.001	<0.001
<b>PVR (ml)</b>			
Mean (SD, range)	158.9 (282.9, 100–2500)	43.8 (54.62, 0–300)	13.15 (19.44, 0–60)
95% CI		(–180.3; –61.2)	(–162.8; –20.4)
<i>P</i> value		<0.001	<0.001
<b>Prostate volume</b>			
Mean (SD, range)	64.35 (32, 20–154)		22.44 (8.26, 8–40)
95% CI			(–46.48; –24.06)
<i>P</i> value			<0.001

*IPSS* International prostate symptom score, *Qol score* Quality-of-life score, *Q max* maximum urinary flow, *PVR* post-voiding residual urine

**Interval Plot of Qmax pre-, postprocedural and ending the follow-up**  
95% CI for the Mean

Individual standard deviations were used to calculate the intervals.

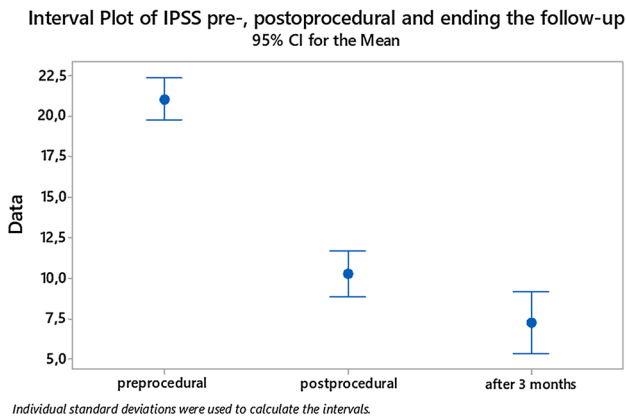
**Fig. 4** Qmax (ml/s): Preoperative, at discharge and after 3 month**Interval Plot of PVR pre-, postprocedural and ending the follow-up**  
95% CI for the Mean

Individual standard deviations were used to calculate the intervals.

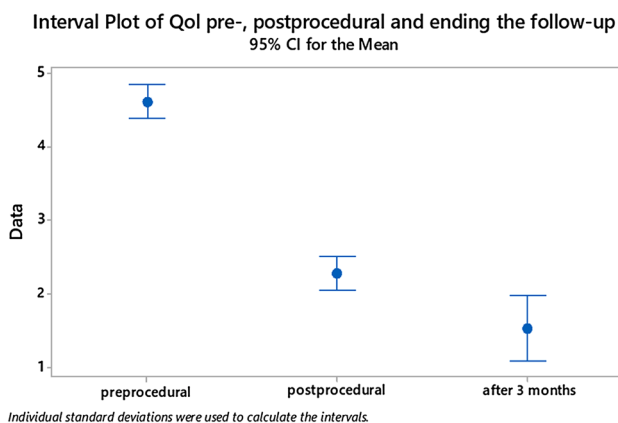
**Fig. 5** PVR (ml): Preoperative, at discharge and after 3 month

Clavien–Dindo scale II (CD II: re-catheterization, transfusion), four patients (3.4%) underwent a secondary surgical intervention needing electrocautery due to delayed haematuria (CD IIIb). One patient revisited hospital ER due to UTI, treated by antibiotics and one with hematuria not needing intervention. Both events occurred 2 weeks after surgery. Table 2 and Figs. 4, 5, 6 and 7 summarize functional outcomes including mean results and 95% CIs at baseline and at the follow-up post procedural.

At 3-month follow-up, TRUS volume decreased by 65% [22.44 (8.26, 8–40)], while mean PSA values decreased from 4.33 to 2.6 ng/ml. 73% of the patients with antegrade ejaculation before surgery reported persistent antegrade ejaculation after Aquablation treatment, as measured with MSHQ-EjD validated questionnaire. So far, no patient required revision due to BPH in this short follow-up period, and no patient is using medication for voiding complaints at 3-month follow-up.



**Fig. 6** IPSS (points): Preoperative, at discharge and after 3 month



**Fig. 7** QoL (points): Preoperative, at discharge and after 3 month

## Discussion

Transurethral resection of the prostate (TUR-P) is the reference treatment of BPH. However, it has relevant size-dependent morbidity and a long learning curve. Laser-based treatment options have reduced the morbidity, and endoscopic enucleation of the prostate offers a size-independent transurethral treatment option [3, 4, 18] but still without relevant reduction of the learning curve.

As shown in prospective RCT in well-defined patient groups, Aquablation of the prostate offers a size-independent, rapid and effective procedure for the surgical treatment of BPH. Translation into daily routine and demonstration of efficiency and safety in a non-selected patient cohort is necessary. Due to image-guided, robot-controlled resection of the tissue, the learning curve is minimized and mainly an expression of OR time, as reported above.

Aquablation treatment of BPH was initiated in 2013 when Gilling and co-workers treated the first patients and reported the first functional outcomes of this novel treatment [15].

Since then, multiple trials have proven efficacy and safety of this procedure. Gilling's group reported data from a phase II study (12-month follow-up period) including 21 men undergoing Aquablation, showing a statistically significant amelioration of IPSS (23.0 to 6.8,  $p < 0.001$ ), QoL (improvement  $> 3$  points,  $p < 0.001$ ), Qmax (8.7 ml/s to 18.3 ml/s,  $p < 0.001$ ) and a decrease of prostate volume (53 ml to 35 ml,  $p < 0.001$ ). Urodynamic outcomes showed a reduction in detrusor wall pressure at Qmax (64 cm H<sub>2</sub>O to 39 cm H<sub>2</sub>O ( $p < 0.001$ )) [16].

The WATER study, a double-blind, multicentre, prospective, randomized, controlled trial, including 181 patients with moderate–severe lower urinary tract symptoms due to benign prostatic hyperplasia comparing transurethral prostate resection with Aquablation of the prostate arrives in the conclusion that both treatments significantly improved BPH symptoms, with Aquablation being non-inferior to TUR-P in this primary outcome endpoint. Aquablation of the prostate appears superior in terms of IPSS improvement in large prostate volume ( $> 50$  ml) compared to TURP ( $p < 0.01$ ). Both treatment groups showed an improvement in maximal urinary flow (Qmax) with a mean Qmax score of 22 ml/s. Moreover, the Aquablation group reveals a significantly lower rate ( $p < 0.001$ ) of sexual dysfunction compared to TURP at 3 months. Besides, Aquablation showed superiority in ejaculatory function and incontinence rates [17].

Desai et al. conducted a prospective multicentre international clinical trial (WATER II), and likewise reported a consistent improvement of IPSS, QoL and Qmax and reduction of PVR [19]. Desai et al. also published similar functional outcomes in a single institution clinical trial which included 47 patients after Aquablation of the prostate [20].

In line with previously reported data, we could confirm a statistically significant improvement of IPSS, Qmax, QoL, and PVR. TRUS-volume reduction of 65% is superior to the reported volume reduction after TUR-P [21] and in line with data published on HoLEP [22] suggesting complete removal of the adenoma.

Regarding the procedure time, Gilling et al. report a mean procedure time of 38 min with a mean ablation time of 5 min [23]. In our study, the mean Aquablation resection time was 3.2 min only, with a shorter overall procedure time. After the initial fifty cases, total procedure time was as low as 17.0 min on average, showing the efficacy of robot-controlled Aquablation and superiority compared to all other surgical treatment options. The transurethral catheter was removed the day after surgery in 19/21 patients [23]. Respective WATER (30–80 cc prostates) and WATER II (80–150 cc prostates) studies presented a mean resection time of 4 and 7 min. with mean hospitalization after the procedure of 1.4 and 1.6 days, respectively. In prostates  $< 80$  cc, 78% of patients were discharged without a catheter [17]; however, in prostates  $> 80$  cc, the majority of the patients (62%) were

discharged home with a catheter [19]. The transurethral catheter was removed in our collective 2.2 days after the procedure on average, resulting in 95% of the patients discharged home without a catheter, although a high number of patients were on indwelling Foley catheter due to recurrent urinary retention. The catheter was removed successfully in the remaining patients during follow-up.

As shown in the WATER study, Aquablation is achieving lower rates of adverse events. In particular, Clavien-Dindo Grade I (CD I) complications (contained dysuria, sexual/ejaculatory dysfunction, urinary incontinence) occur significantly less after Aquablation [24]. The CD II+ rates were similar in TUR-P and Aquablation groups (23% vs. 20%, respectively) [17]. The WATER II study reports that CD II+ side effects were about 30%. Significant bleeding was recorded in 10% of the patients, while six patients received a blood transfusion during the procedure or the hospitalization. In our study hemoglobin levels decreased from a mean of 14.2 g/dl at baseline to 12.42 g/dl postoperatively, leading to three patients (2.5%) with the need for transfusion, due to clinical relevant symptoms of blood loss, and a total number of adverse events larger than CD I of only 13 (11%). There were fewer events CD II+ than in published trials and might also be an expression of growing experience and standardized perioperative care, e.g., administration of tranexamic acid before the procedure or standardized catheter handling, including the use of the CTD.

## Conclusion

The strength of our study is the inclusion of the so far largest number of consecutive patients from a single center in real practice. The wide range of prostate volumes, representative of the inclusion criteria of WATER and WATER II and avoiding strict exclusion criteria, like chronic urinary retention allows the conclusion that it is safe and efficient to include Aquablation treatment into clinical routine, without compromising the functional outcomes as reported in RCTs. Maintaining high rates of antegrade ejaculation is in favor of patient demands. A volume reduction superior to TUR-P and comparable to endoscopic enucleation suggests durability of this young and innovative approach, despite the so far missing follow-up data in larger patient groups over 1 year. The presented results indicate the potential in BPO treatment that this novel approach might offer in the near future.

**Author contributions** TB protocol and project development, data analysis, manuscript writing. GG manuscript writing and editing, data analysis. AB interpretation of data, critical revision of the manuscript. CF interpretation of data, critical revision of the manuscript. FGS interpretation of data, critical revision of the manuscript. TRWH interpretation of data, manuscript editing. CN interpretation of data, critical revision of the manuscript. MR interpretation of data, critical revision

of the manuscript. CMS interpretation of data, critical revision of the manuscript. LT interpretation of data, critical revision of the manuscript. JJR interpretation of data, critical revision of the manuscript. EL interpretation of data, critical revision of the manuscript

## Compliance with ethical standards

**Conflict of interest** TB: Advisory, speakers honoraries, trial participation, meeting participation: R. Wolf, PROCEPT Biorobotics, Boston Scientific. TRWH: Company consultant, advisory, patent, royalties, speakers honoraries Karl Storz, LISALaser, Advisory, speakers honoraries, travel grants, Boston Scientific Advisory, speakers honoraries. Other authors declare that they have no conflict of interest and nothing to declare in regards with this manuscript. This is a series of consecutive patients treated with in clinical routine. The study was approved by IRB and local ethics committee. All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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