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# The Butterfly: A Novel Minimally Invasive Transurethral Retraction Device for Benign Hypertrophy of the Prostate

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**Keywords**
Benign prostatic hyperplasia · Lower urinary tract symptoms · Bladder outlet obstruction · Minimally invasive surgical therapy · Urethral devices

**Abstract**
***Introduction:*** The Butterfly Prostatic Retraction device is a novel transurethral implant designed to dilate the prostatic urethra and treat lower urinary tract symptoms. We assessed its safety, efficacy and impact on urinary flow, ejaculation, and quality of life. ***Materials and Methods:*** We included 64 men, treated for benign prostate hyperplasia for at least 1 year. All patients had Qmax≤ 13 mL/s and IPSS >12. Insertion of the device was performed via cystoscopy. Follow-up visits were performed at 2 weeks, 1, 3, 6, and 12 months and included uroflowmetry, IPSS, QoL, and sexual function questionnaires. Cystoscopy was performed on 3 and 12 months. ***Results:*** Patients age was 50–83 years. 28 patients completed a 1-year follow-up with an intact device. Mean Qmax improved by 2 mL/s (25%), IPSS median drop was 10 points (40%), and QoL score was 1.5 points (38%). Sexually active patients reported antegrade ejaculation. On cystoscopy, gradual coverage of the devices with urethral mucosa was observed. In 1 patient, the device was repositioned. In 19 patients, the device was removed. 12 patients returned to alpha-blocker therapy and 7 patients underwent TURP. One patient developed a bulbar urethral stricture. ***Conclusions:*** We demonstrated feasibility and good tolerability of the Butterfly device.



## Introduction

Benign prostatic hyperplasia (BPH) is the most common etiology of bladder outlet obstruction and voiding dysfunction in men [1–4]. Common treatment strategies for BPH include medical therapy with alpha-blockers and 5-alpha reductase inhibitors (5-ARIs). Patients who failed medical therapy were traditionally referred for surgery. During the last decades, various minimally invasive surgical therapies were introduced to treat BPH including urethral thermotherapy, prostate ablation, prostate artery embolization, and prostatic stents [5].

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Early urethral stents were designed for elderly fragile patients and were abandoned due to significant stent-related morbidity [5–9]. During the last decade, intraprostatic devices such as the prostatic urethral lift, ProArc clear ring, and iTIND were introduced with encouraging short to mid-term clinical results [10–12].

The Butterfly Prostatic Retraction device (Butterfly Medical, Yokneam, Israel) is a transurethral device, placed in the prostatic urethra, and designed to push laterally the prostate lobes. We present our experience with the Butterfly device in men suffering from symptomatic BPH.

## Materials and Methods

*Device Design*

The Butterfly consists of two lateral wings connected by transverse arches and is available in 5 sizes. The device is attached to two pusher tubes. The tubes are hollow and fine string loops run through each of them and encircle the distal aspect of the Butterfly on each side (Fig. 1).

The Butterfly implant is folded into a 5-mm introducer. It is inserted through a rigid cystoscope and deployed in the prostatic urethra between the verumontanum and the bladder neck. In body temperature, the device expands and pushes the prostate lobes laterally.

*Study Design*

The study was approved by the hospitals' IRBs (0073-17-ZIV) and registered in Clinical Trials.gov (NCT 03912558). We enrolled men above 50 years of age, treated for BPH for at least 1 year, with a prostate size between 30 and 110 g, Qmax below 13 mL/s, and IPSS score above 12. All patients were eligible candidates for prostate surgery but elected to take part in the study. No patient suffered from urinary retention, and no patient had an indwelling catheter. We excluded patients with active prostatitis, urethral or bladder neck pathology, enlarged median lobe, previous prostate surgery, and atonic bladder. All patients signed an informed consent form before entering the study. Patients were followed for a period of 1 year after insertion of the device. The study's objectives were assessment of the safety and efficacy of the Butterfly, assessment of life quality, sexual and ejaculatory function, and visual assessment of the device's position and encrustation status.

Urinary symptoms were assessed using the IPSS questionnaire. Sexual activity status was assigned as follows: 1. no erection; 2. erectile dysfunction; and 3. normal spontaneous erections. Ejaculatory status was defined as follows: 1. antegrade ejaculation; and 2. retrograde or un-ejaculation.

Patients' evaluation included uroflowmetry and sonography examination including measurements of prostate size and urinary residual volume. Flexible cystoscopy was performed in order to evaluate urethral patency, identify a median prostate lobe or bladder neck pathology, and measure the length of the prostatic urethra. The lengths and their adequate device size were defined as follows: 2–2.5 cm (small), 2.5–3 cm (medium), 3–3.5 cm (medium/large), 3.5–4 cm (large), and 4+ cm (X large). A sterile urine culture was a prerequisite before the procedure. Patients were allowed to continue their BPH therapy until the day of the procedure and there was no drug "wash out" period.

**Fig. 1.** The Butterfly device.

*The Procedure*

Procedures were performed under sedation or general anesthesia. Patients were placed in the low lithotomy position and given a single dose of Garamycin 7 mg/kg and Cefazolin 2g. A 22 Fr. Cystoscope was used (Karl STORZ, Germany) also. The irrigation solution was chilled to 5–10°C, causing the device to soften due to the thermal properties of the nitinol.

Rigid cystoscopy was performed up to the bladder neck. The delivery sheath with the Butterfly was inserted through the scope. The Butterfly was deployed and was pulled back to the desired location between the bladder neck and the verumontanum.

The irrigation fluid was switched to a room temperature saline causing the device to expend. Once properly positioned, the implant was detached from the pusher tubes. No catheter was left.

Patients were discharged after voiding. Oral pain medications and Phenazopyridine to relief dysuria were given to PRN.

*Follow-Up*

Patients were followed after 2 weeks, 1, 3, 6, 9, and 12 months. In each visit, the patients filled the IPSS questionnaire, reported their erectile and ejaculatory status, performed uroflowmetry, urinary residual measurement, and a urine culture. At 3 and 12 months, flexible cystoscopy was performed.

*Statistics*

Study data were summarized and tabulated. Continuous variables (e.g., uroflow) were summarized by the mean, median, range, standard deviation, and the interquartile range (IQR). Categorical variables (e.g., adverse events) were presented in tables that listed count and percent. The study was not powered for statistical significance. Correlation was assessed using the Pearson coefficient.

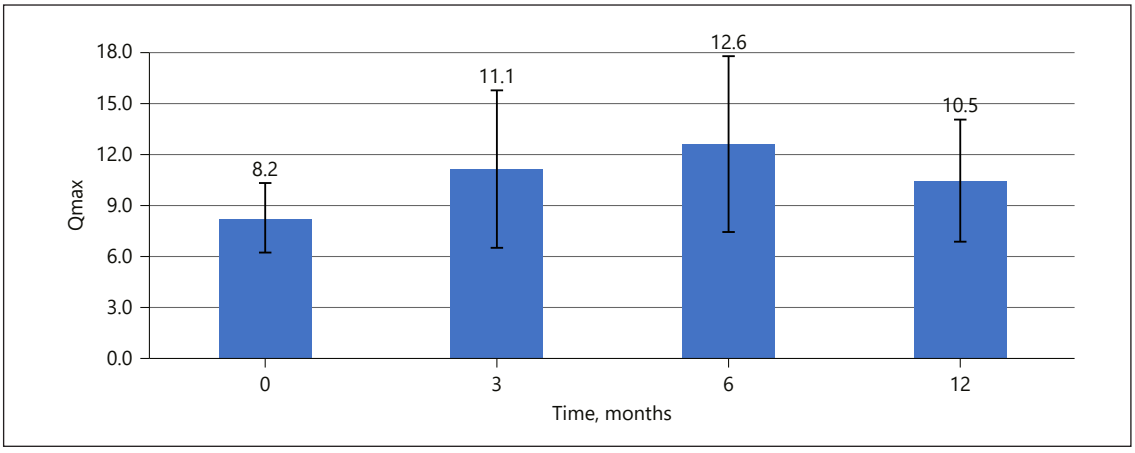


**Fig. 2.** Average Qmax of 28 patients during 1-year period.

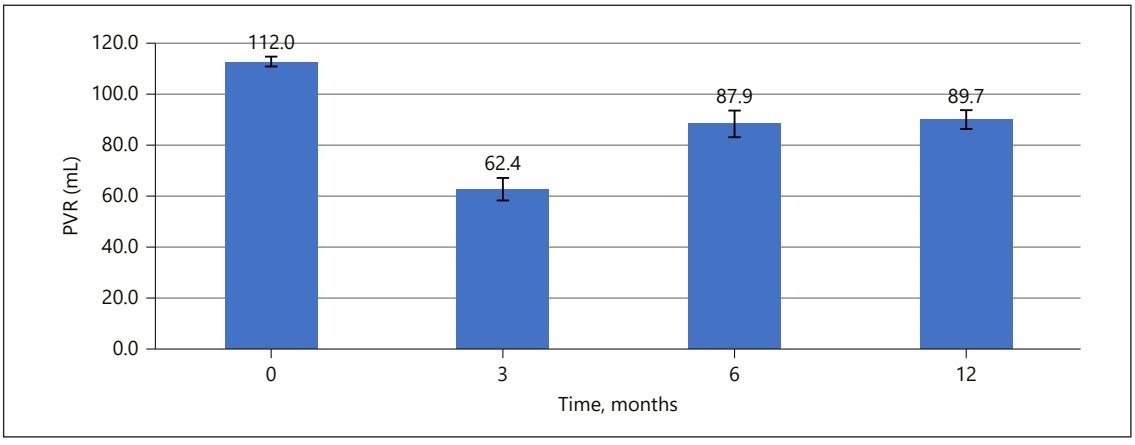


**Fig. 3.** Average PVR of 28 patients during 1-year period.

## Results

Between October 2018 and July 2021, 64 men underwent implantation of the Butterfly device. Patients mean age was 68 years (median 68.5, range 50–83, IQR 65–73). Ten patients were older than 75 years. Follow-up period ranged from 4 to 35 months. Twenty-eight patients completed a 1-year follow-up with an intact device.

Mean prostate volume was 52.9 mL (range 30–109, median 45, STD 21, IQR 38–61). The choice of device size was based upon the prostatic urethra length rather than the prostate volume. We found that the prostate volume had a low correlation with the urethral length (Pearson correlation coefficient test, $r = 0.32$). The common urethral lengths were 2–2.5 and 2.5–3 cm, corresponding to a small and medium size implants.

Procedure time (from cystoscopy and urethral length measurement to deployment of the device and retraction of the scope) decreased rapidly. The longest procedure took 50 min and the shortest procedure took 3 min (Median OR time - 9 min, IQR 6–14).

Proper positioning of the device was achieved in 63 patients. In 1 patient, a 50-year-old man with a short prostate and a prominent bladder neck, we were not able to place the device and the procedure was aborted.

Migration of the device into the bladder was noted in 3 patients. In the first patient, the device was retrieved and a new one was placed with an excellent postoperative course. The 2 other patients elected to return to alpha-blocker therapy, and their devices were removed uneventfully.

19 patients had their devices removed between 2 weeks and 9 months after the implantation (mean 3.9 months). In 7 of them, the devices were removed due to voiding

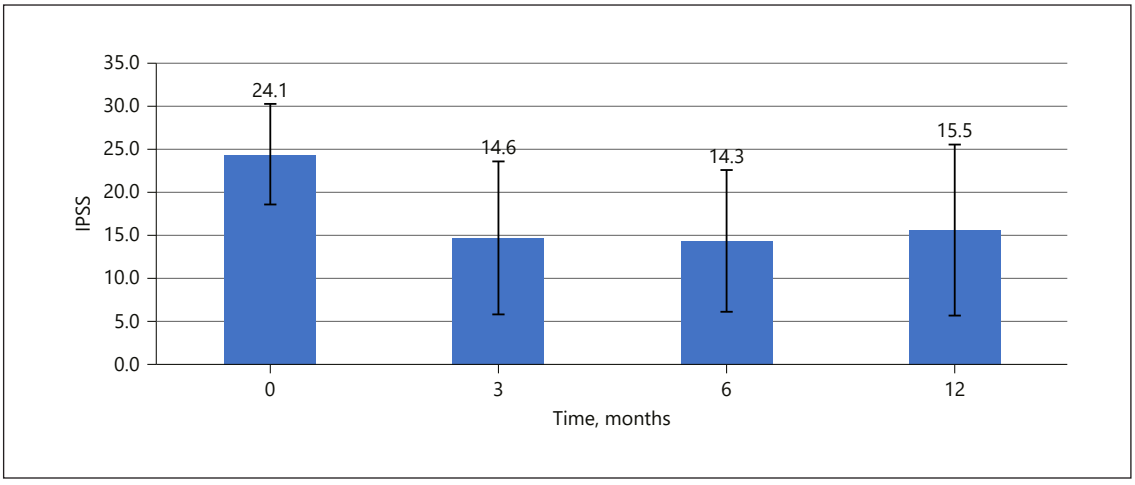


**Fig. 4.** Average IPSS of 28 patients during 1-year period.

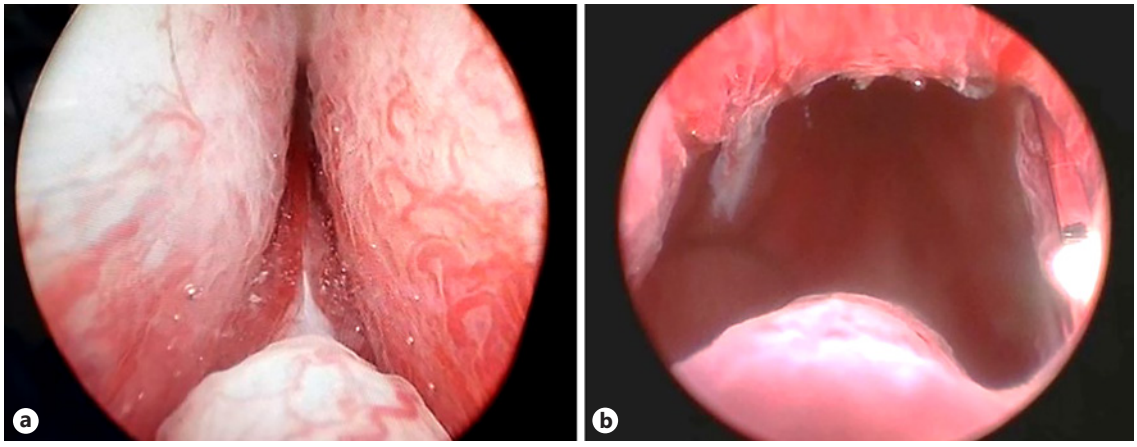


**Fig. 5.** An endoscopic view of the prostatic urethra before and 6 months after implementation of the Butterfly.

difficulties, and they subsequently underwent TURP. In 5 patients, the devices were removed due to dysuria, 5 patients failed to adhere to the study protocol, and 2 had device migration.

*Sexual Function*

30 patients reported good erection and sexual function before the procedure; they all remained potent after the procedure. Out of 34 patients who were not sexually active before the procedure, 13 patients reported return of complete sexual activity, mainly due to the cassation of 5-ARIs therapy.

Preoperatively, 22 patients reported ejaculatory dysfunction. Following the procedure, 11 patients reported the return of antegrade ejaculation.

*Functional Outcomes*

Twenty-eight patients completed a 12-month period with an intact device. Their mean baseline Qmax was 8.2 mL/s, and the mean improvement in Qmax was 2.3 mL/s (25%) in 12 months (Fig. 2).

Mean PVR was 112 mL on baseline and decreased to 89.7 mL in 12 months (20% decrease) (Fig. 3). Mean IPSS score was 25 on baseline and 15 after 12 months (40%). 71.4% of all the patients had an IPSS decrease of more than 3 points (Fig. 4). The mean improvement of QoL was 1.5 points (38%).

*Technical Aspects*

During follow-up cystoscopies, a flexible scope was passed into the bladder through the device. The majority

of the devices were well positioned creating a large channel in the prostate up to the bladder neck. The devices were gradually covered by the mucosa, and there were no encrustations. In the patients that underwent TURP, pathologic analysis revealed BPH tissue, with no significant findings (Fig. 5).

*Complications*

There were no intraoperative complications. Perioperatively, 3 out of 64 patients had a Clavien Dindo grade 3a complication (urinary retention requiring suprapubic drainage).

*Urinary Retention*

The patients were left without a catheter. 10 patients had urinary retention in the recovery room. We treated the 3 first cases with suprapubic drainage for 24–72 h. Later, we found that a lubricated 10.

Fr. Nelaton catheter could be passed through the Butterfly device and a single catheterization was sufficient for the other 7 patients. One patient went into retention 1 month after the procedure, had a suprapubic catheter, and underwent TURP.

*Urinary Infection*

All patients underwent the procedures with sterile urine culture and under prophylactic coverage of intravenous Garamycin and Cefazolin. Only one case of a febrile urinary tract infection with *E. coli* was noted, which resolved after antibiotic treatment. Repeated urine cultures of this patient were sterile.

*Minor Adverse Events*

Mild dysuria, urinary frequency, and urgency were also noted during the first 4 weeks after the procedure.

*Major Adverse Events*

One patient developed a 1-cm bulbar urethral stricture. The patient underwent successful urethroplasty. He voids spontaneously and still carries the device.

## Conclusion

BPH is the most common cause of lower urinary tract obstruction and symptoms in aging men [1]. Medical therapy is effective in relieving LUTS. Alpha-blockers are the mainstay of therapy, showing improvement in life quality and good tolerability. Their major side effect is ejaculatory dysfunction, reported in up to 26% of the patients [13–15].

5-ARIs are effective in decreasing the prostate volume and the risk for subsequent prostate surgery. Their side effects include decreased libido, erectile and ejaculatory dysfunction, and gynecomastia [16].

Patients who failed medical therapy are traditionally referred for surgery. In an effort to bridge between medical to surgical therapy, various minimally invasive surgical therapies were developed, including prostatic stents and retraction devices [17, 18].

The Urolume wallstent was developed for elderly fragile patients and designed of stainless steel mesh. Short-term experience reported good results in terms of Qmax, IPSS, and urinary residuals [19] but long-term follow-up revealed that almost half of the stents had to be removed due to malpositioning or progressive obstruction [20, 21]. Other stents, as the Memokath and Memotherm, showed similar results [22, 23].

The UroLift device has been shown to be a well-tolerated, minimally invasive therapy for BPH [10]. It retracts the lateral lobes of the prostate using a set of stainless steel anchors.

In the LIFT study, 131 patients showed a 33% decrease in IPSS scores, a 44% improvement in QoL scores, and approximately 50% improvement in Qmax in 1 year [24]. In comparison, the Butterfly device showed a 40% decrease in IPSS scores and a 38% improvement in QoL as well as 25% improvement in Qmax. In both devices, no de novo erectile or ejaculatory dysfunctions were reported.

Common adverse effects of the UroLift included mild to moderate hematuria in up to 80% of the patients, dysuria (74%), irritative symptoms/discomfort (52%), urinary tract infection (11%), and urinary retention (9%). Encrustations were noted in 2% of the anchors that were placed at the bladder neck. During a 5-year follow-up, 13.1% of patients failed and required additional treatment [25]. In the Butterfly device, no hematuria was noted; mild dysuria was reported by most of the patients, urinary infection occurred in 1.5%, and urinary retention in 15.1%. 10.9% of the patients required TURP.

The iTind is a nitinol device comprised of three elongated struts, an anchoring piece, and a retrieval string. It exerts local pressure over the prostate and the bladder neck, leading to ischemic tissue changes. Unlike the Butterfly, it is removed after 5–7 days. In a randomized trial, the iTind showed a reduction of 9.25 points in the IPSS score, an improvement of 3.52 mL/s in peak urinary flow, and 1.9 reductions in QOL score [11].

The ProArc Clear Ring device is a nitinol C shape retraction device. In contrast to the Butterfly, the ProArc is available only in one size, and an incision is required in order to implant it into the mucosa. In a series of 29 patients, 18 patients showed improvement in Qmax and IPSS scores in 1 year but implantation failed in 11 patients (37.9%) [12].

The Butterfly device is available in 5 length sizes and therefor suites a wide range of prostates. The largest prostate that we treated in this study was 109 g, compared to 60–80 g in the UroLift studies.

Migration of the device was observed in 3 patients (6%). Older stents series report migration and malpositioning in 29–37% of the patients [20]. The UroLift is composed of a series of tissue anchors that should not migrate but detachment of these anchors and treatment failure was reported in up to 13% of the patients [25].

Encrustations were not noted on any of the butterfly devices, even not on those that migrated into the bladder, probably due to good coverage with the mucosa and the physical properties of nitinol. The procedure is easy to perform with a short learning curve. OR time decreased from 50 min in the first cases to 9 min on average, and the shortest cases took 3 min. We performed the procedures under sedation or anesthesia under day care settings. We believe that with additional experience, this procedure could be performed under local anesthesia and would be suitable for in office use.

Looking at the functional results, the mean improvement in Qmax was 2 ml/s (40%), compared to 50% improvement in the Rezum studies [26] or 4.1 mL/s (46%) in PAE study by Ray et al. [27]. Yet in these studies, all the patients underwent a washout period before the procedure, which probably worsened their flow and symptoms, while we treated these patients as any other patients scheduled for TURP and allowed the use of alpha-blockers and/or 5-ARIs until the procedure. If we had performed a washout, the difference between pre- and posttreatment would have been significantly bigger. We also took patients with a Qmax of up to 12 mL/s (compared to 15 in the Rezum study) and prostate size up to 100 g (compared to 80 in the Rezum study).

The Butterfly can be retrieved at patients' request. We used rigid cystoscopy and chilled saline solution to soften the device and alligator forceps to grasp the anterior arch of the device and pull it through the rigid scope sheath. TURP can be immediately performed if planned.

We removed 19 devices (30%). Most of them were early cases at the beginning of our learning curve and removed due to patients' dissatisfaction and discomfort. There were no cases of recurrent urinary retention with the device. In our current practice, we see significantly less removals. It should be emphasized that the Butterfly device is easy to retrieve, especially during the first 6 months after insertion, and all participants were guaranteed that we will remove it if they request.

Early prostatic stents were mainly designated for old and fragile patients. In contrast, modern prostatic devices are designed for younger patients who wish to retain ejaculatory and erectile function. In our series, we treated patients as young as 50 years, and the major reason for applying to the study was patients' wish to stop 5-ARIs therapy. Out of 34 patients who were not sexually active, 13 patients who stopped 5-ARIs reported the return of spontaneous erections, and most of sexually active patients reported antegrade ejaculation.

Minimally invasive procedures for BPH were developed in order to relief BPH-related symptoms, decrease the risks of surgical interventions, and minimize hospital stay while keeping a durable response. Early urethral devices were wall mesh stents made of stainless steel developed for elderly and fragile patients. They were abandoned due to a high rate of obstruction, encrustation, and migration.

Modern urethral devices are nitinol based. They are designed for younger, active patients, who wish to avoid surgery and retain sexual and ejaculatory function.

Ten patients were older than 75 years old. These patients, in the geriatric age group, are more vulnerable. Prostatic stents were initially designed for elderly and fragile patients. All the 10 patients in this group did well without any need for further intervention.

Altered coagulation and anticoagulant therapy was a contraindication for inclusion in this study yet treatment with Aspirin 100 mg was not. The Butterfly device can be safely implanted in patients on Aspirin.

The Butterfly device allows rapid relief of prostatic obstruction while maintaining antegrade ejaculation. It is ideal for day care settings and showed a good clinical response with an acceptable rate of complications. Further studies are required to assess its long-term effectiveness.

## Statement of Ethics

This study protocol was reviewed and approved by Ziv Medical Center IRB, approval number 0073-17-ZIV and registered in Clinical Trials.gov (NCT 03912558). Written informed consent was obtained from all participants before entering the study.

## Conflict of Interest Statement

The authors have no conflicts of interest to declare.


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This study was fully funded by Butterfly Medical Ltd. Yoqneam, Israel. The coverage included all hospitalization costs as well as the device itself. Patients or their medical insurance did not pay anything in this study. The company and it's representatives did not take any part in preparing this manuscript.

## Author Contributions

Study performance: Ran Katz, Muhamad Abu Ahmed, Ali Safadi, Shmuel Roizman, Amnon Zisman, Maharan Kabha, Yoram Dekel, Jack Baniel, and Shachar Aharony. Study design: Ran Katz and Shachar Aharony. Data analysis: Ran Katz, Shachar Aharony, and Shmuel Roizman. Ran Katz wrote the paper.

## Data Availability Statement

This study's data are available at request from the first author. All data are collected on file with Butterfly Ltd., Yoqneam, Israel and therefore does not appear freely on the internet or other public resources. However, all the data will be available at request.

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