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Comparing silicone-coated self-adhesive absorbent polyurethane films with transparent absorbent films for bilateral hip dressing: a prospective randomized controlled trial

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Abstract

Background Silicone-coated self-adhesive absorbent (SSA) and transparent films with absorbent (TFA) dressings are reportedly effective postoperative knee surgery dressings; however, there have been no direct comparative studies on these two innovative dressings over the hip areas. In this study, we aimed to compare user satisfaction and potential complications between TFA and SSA dressings for the hip area.

Methods This prospective randomized controlled trial was conducted at a tertiary hospital. The hip side to receive the polyurethane film with SSA dressing (Mepilex® Border Post-Op) was randomly allocated. The other side of the hip was covered with TFA (OPSITE Post-Op). Participants were scheduled for follow-ups 7 and 14 days after the initial application. Between-group outcomes were compared using a two-sample t-test or Wilcoxon signed-rank test for continuous variables and McNemar's chi-square test for categorical variables.

Results Thirty-two participants (30 – 60 years) without a history of hip surgery were included in the study. The participants were predominantly female, with a mean age of 42.8 years. Pain, difficulties in daily activities, and satisfaction scores were similar between the groups. However, moisture accumulation was significantly higher with the TFA dressing (37.9% vs. 13.8%, $p < 0.01$), with more dressing failures (34.5% vs. 20.7%, $p = 0.016$) and complications (37.9% vs. 17.2%, $p = 0.012$) at the 14-day follow-up than with the SSA dressing.

Conclusions SSA dressings are preferable for hip wound care because of better moisture management, fewer dressing changes required, and fewer complications if applied for > 7 days. Both dressings offered high user satisfaction, minimal pain, and minor difficulties in daily activities.

Keywords Mepilex, OPSITE, Dressing, Hip

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Background

Wound dressing and closure are critical steps in patient care, particularly for patients undergoing surgery. The main objectives of surgical wound dressing are to aid wound healing and prevent complications resulting from the wound [1]. These complications can lead to increased hospital stays and higher treatment costs [2]; therefore, it is important to choose an appropriate wound dressing for each patient. First, the quality of the dressing material should be considered. The desirable properties of dressing materials include the ability to absorb fluids draining from the surgical wound, prevent microbial contamination, and promote faster wound healing [3, 4]. Second, the location of the wound dictates the type of material to be used based on its elasticity. Wounds around highly mobile areas, such as the knees or hips, require dressing materials with high elasticity to reduce skin tension and allow free movement without dislodging easily [5].

For postoperative wound dressing, there are several proven advantages of innovative wound dressings compared to conventional wound dressings with gauze [6, 7]. The OPSITE Post-Op is an innovative wound dressing that is generally used in orthopedic patients [8]. This dressing has an absorbent pad with transparent film, which reduces the need for changing the dressing, and decreases the rates of blistering and wound discharge [9]. Mepilex® Border Post-Op was designed to combine characteristics of high flexibility and elasticity, good adhesion to the skin, absorbent ability to reduce the risk of skin complications, and adequate barrier/waterproof function [10, 11]. In addition to the performance of each dressing, the pain in dressing application and removal, difficulty during activities while using the dressing, and user satisfaction should be considered as they may affect overall outcomes.

Previous studies have revealed that silicone-coated self-adhesive absorbent (SSA) and transparent films with absorbent (TFA) dressings are effective postoperative knee surgery dressings [12–14]; however, there have been no direct comparative studies on these two innovative dressings over the hip areas. Thus, this study aimed to compare user satisfaction and potential complications between SSA and TFA dressings on the hips.

Methods

Study design

This prospective, randomized, controlled, interventional, single-blind trial was performed at a tertiary hospital to compare user satisfaction and potential complications between SSA and TFA dressings on the hips. We included participants with simulated posterior-approach hip surgical wounds. The Institutional Review Board approved the study protocol (REC. 66-488-11-1) and was registered in the Thai Clinical Trials Registry (TCTR20240319010). The procedures were performed in accordance with the ethical principles of the Declaration of Helsinki for medical research involving human participants. Written informed consent was obtained from all participants before their participation in the study. All participants were enrolled following the Consolidated Standards for Reporting Trials (CONSORT).

Participants

Between March and June 2024, participants aged 30–60 years with no history of hip surgery were enrolled. The exclusion criteria were participants with lower limb pain or radicular pain and weakness and participants with skin lesions over the hip area or allergy to any of the dressing products.

Randomization

The hip side to receive the SSA dressing (Mepilex® Border Post-Op) was randomly allocated. The other side of the hip was assigned to receive TFA dressing (OPSITE Post-Op dressing). Block-of-four randomization with computer-generated random numbers was used to allocate the hip side to each participant. The randomization envelopes were opened just before applying the wound dressings to reveal the side assignment for the dressing type. Finally, the dressings were applied to simulated wounds on both hips of participants.

Wound dressings

The SSA wound dressing investigated in this study was Mepilex® Border Post-Op (10 cm x 25 cm; Mölnlycke Health Care AB, Gothenburg, Sweden). It is a sterile, absorbent foam wound dressing incorporating soft silicone Safetac®-coated polyurethane film technology, which helps to minimize pain and trauma at removal. The TFA dressing used as a control was OPSITE Post-Op (10 cm x 25 cm; Smith & Nephew Advanced Wound Management, Hull, UK), which is the standard dressing for postoperative hip replacement surgery in our hospital. This is a postoperative film dressing with a low-adherent absorbent pad. Both wound dressings have a transparent layer around the edge and are waterproof; thus, it may not be necessary to reapply the dressing after showering or change it daily [12].

Intervention

Skin conditions over the hip area were assessed before wound dressing. Registered nurses who had worked in the orthopedic outpatient department for >5 years and were uninvolved in the research applied the designated dressings at the posterior to the lateral side of the hip. For simulating the posterior approach hip surgery wounds, the straight incision was simulated on the femoral-iliac line, which is located between the posterior superior iliac

spine and the middle of the femoral shaft. The starting point was 4-cm proximal, and the endpoint was 4-cm distal from the tip of the greater trochanter [15]. Then, the SSA dressing was applied first, followed by the TFA dressing; both were used in accordance with the manufacturers' instructions. The fugures illustrating the placement of the dressings over the hips were provided as a supplementary file. Following the dressing application, an orthopedic doctor specializing in hip arthroplasty checked and confirmed whether the dressings were applied at the correct location on both hips. Next, a research assistant, who was blinded to the dressing type and did not know which side of the hip was applied TFA or SSA, interviewed each participant in a private room in the outpatient department of the orthopedic clinic for approximately 10–15 min to collect data on their satisfaction with the dressings. The research team scheduled follow-up appointments with the participants 7 and 14 days after the initial dressing application. Interviews and data collection on satisfaction and complications were repeated at each visit.

Outcome measures

At the initial visit, participants' demographic information and medical history were recorded and both hips were evaluated. The primary outcome was participant satisfaction assessed at the day 7 follow-up. This assessment included the level of pain experienced during dressing application and any difficulties encountered in daily activities, such as transferring positions, ambulation, toilet use, bathing, and climbing stairs. The degree of pain and difficulties in daily activities were recorded by using Numeric Rating scales, which range from 0 (best) to 10 (worst). Also, overall satisfaction with each dressing type was evaluated and recorded on a scale of 0 (worst) to 10 (best). The secondary outcomes were any complications potentially arising from wound dressing application, such as pruritus, abrasion, erythema, redness, or blister formation. Additionally, the presence of moisture was assessed by visual observation. It was identified as moisture when vapor or water droplets under the dressing or dampness of the dressing pad were seen. The dressing failure was also noted if it occurred. It was defined as the dressing becoming ineffective due to adhesive loosening, the transparent film peeling off, or the dressing pad migrating or falling off. On the day 14 follow-up, the pain severity during dressing removal and all parameters previously mentioned for the day-7 follow-up were reassessed. The dressings were changed as needed during each follow-up. The date of dressing failure and total number of dressing changes were recorded. Participants were allowed to withdraw from the study at any time and were asked to explain the reason for their decision to discontinue.

Statistical analysis

R software version 4.0.3 (The R Foundation for Statistical Computing, 2020, Vienna, Austria) was used for statistical analysis. For descriptive outcomes, data are presented as mean ± standard deviation for continuous variables or as median (interquartile range), as appropriate. Categorical variables are presented as numbers and percentages. For comparison between the two dressings, the outcomes were analyzed using a two-sample t-test or Wilcoxon signed-rank test for continuous variables, and McNemar's chi-square test for categorical variables. Statistical significance was set at $p < 0.05$.

Results

In total, we enrolled 32 participants in this study, who were randomized to determine to which side of the hip the SSA dressing would be applied (Fig. 1). At 7-day and 14-day follow-ups, no participant was lost to follow-up. At the first follow-up, three participants reported complications with the TFA dressing during application, including itching, redness, and blebs. All three patients could not tolerate these complications and discontinued the TFA dressing. Therefore, 29 and 32 hips were included in the TFA and SSA groups, respectively, at the final follow-up.

Participant characteristics are shown in Table 1. The study included 32 participants with an average age of 42.8 years (SD = 10.8). Most of the participants were women, making up 96.9% of the group. On average, they weighed 62.6 kg (SD = 10.3), and the height was 158.3 cm (SD = 5.3), with little variation in height. About a third of the participants (31.2%) had more than one underlying disease, with hypertension being the most common, followed by dyslipidemia. At the 7-day follow-up, several outcomes were compared between the two groups (Table 2). Pain during application was similar for both TFA and SSA dressings at 0.16 ± 0.88 and 0.13 ± 0.49, respectively. Difficulties during various activities, including transfer, ambulation, toilet use, bathing, and climbing stairs, were also assessed. There were no statistically significant differences in these activities for both dressings. Overall satisfaction scores were high for both dressings (8.59 ± 1.37 and 8.67 ± 1.70 for TFA and SSA dressings, respectively) and were not significantly different. However, there was a significant difference in the incidence of moisture under the dressing (28.1% for TFA and 21.9% for SSA; $p = 0.006$). Dressing failure rates and complications did not differ significantly between groups.

At the 14-day follow-up, pain during removal was slightly higher in the TFA group than in the SSA group; however, the difference was not statistically significant. Difficulties during activities were also not significantly different from the results at the 7-day follow-up. Overall satisfaction scores showed a non-significant favor

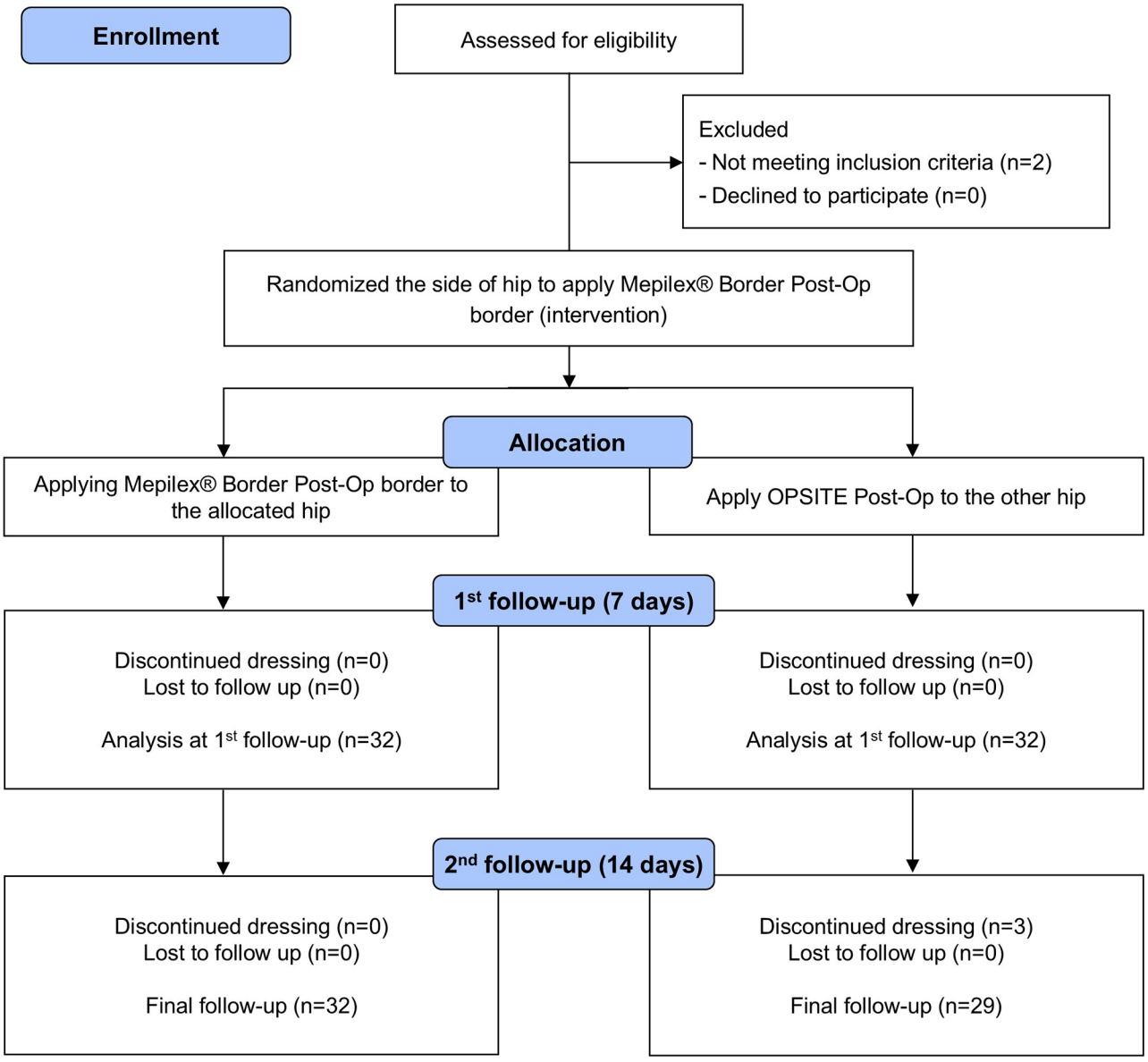

Fig. 1 Study flowchart

Table 1 Participant characteristics

Variables	Participants ($n=32$)
Age (years)	42.8 ± 10.8
Sex (female)	31 (96.9)
Body weight (kg)	62.6 ± 10.3
Height (cm)	158.3 ± 5.3
Underlying disease ≥ 1	10 (31.2)

Data presented as number (%), mean ± standard deviation (SD)

for SSA over TFA ($p=0.073$). Moisture under the dressing was significantly more common with TFA than with SSA dressings (37.9% vs. 13.8%, respectively; $p<0.01$). The average time to the first dressing change was higher for TFA (Median = 7 days) compared to SSA (Median = 5 days). However, the results were not statistically significant with $p=0.229$. Regarding complications, significantly more complications occurred with the TFA dressing than with the SSA dressing (37.9% vs. 17.2%; $p=0.012$) (Table 3). The most common complication was itching, followed by skin redness and blebs.

Regarding the number of dressing failures over 14 days, the total failure rates for TFA and SSA dressings were 62.5% and 46.9%, respectively. One-time dressing failures were experienced by 50% of TFA users and 34.4% of SSA users. Both groups experienced the same rate of two-time failures (12.5%) (Table 4).

Table 2 Comparison of satisfaction, complication, and dressing failure rates between TFA and SSA dressings at 7-day follow-up

Outcomes	Type of dressing		*p* value
	TFA (*n* = 32)	SSA (*n* = 32)	
Difficulties during activity	0.34 ± 1.04	0.16 ± 0.52	0.198
Transfer	0.31 ± 0.99	0.19 ± 0.54	0.410
Ambulation	0.63 ± 1.26	0.31 ± 0.64	0.545
Toilet use	0.75 ± 1.37	0.53 ± 0.88	0.152
Bathing	0.22 ± 1.07	0.13 ± 0.49	0.789
Stair climbing			
Overall satisfaction	8.59 ± 1.37	8.67 ± 1.70	0.775
Moisture under dressing	9 (28.1)	7 (21.9)	0.006*
Dressing failure	14 (43.8)	12 (37.5)	0.361
Occurrence of complication	15 (46.9)	10 (31.2)	0.248

Data presented as number (%), or mean ± standard deviation (SD)

TFA: transparent film with absorbent dressings; SSA: silicone-coated self-adhesive absorbent dressings. *p value < 0.05 is considered statistically significant

Table 3 Comparison of satisfaction, complication, and dressing failure rates between TFA and SSA dressings at 14-day follow-up

Outcomes	Type of dressing		*p* value
	TFA (*n* = 29)	SSA (*n* = 29)	
Difficulties during activity	0.24 ± 0.99	0.07 ± 0.37	1
Transfer	0.17 ± 0.66	0.07 ± 0.37	1
Ambulation	0.31 ± 0.60	0.27 ± 0.65	0.773
Toilet use	0.35 ± 0.61	0.35 ± 0.67	1
Bathing	0.21 ± 1.11	0	1
Stair climbing			
Overall satisfaction	8.55 ± 1.30	9.03 ± 0.98	0.073
Moist under dressing	11 (37.9)	4 (13.8)	0.006*
Dressing failure	10 (34.5)	6 (20.7)	0.016*
Time to first dressing change (day)	6.41 ± 4.12	4.87 ± 2.95	0.229
Occurrence of complication	11 (37.9)	5 (17.2)	0.012*

Data presented as number (%), or mean ± standard deviation (SD)

TFA: transparent film with absorbent dressings; SSA: silicone-coated self-adhesive absorbent dressings. *p value < 0.05 is considered statistically significant

Table 4 Dressing failure rates at the 14-day follow-up

Number of dressing failures	Type of dressing	
	TFA (*n* = 32)	SSA (*n* = 32)
0	12 (37.5%)	17 (53.1%)
1	16 (50.0%)	11 (34.4%)
2	4 (12.5%)	4 (12.5%)

Data presented as number (%)

TFA: transparent film with absorbent dressings; SSA: silicone-coated self-adhesive absorbent dressings

Discussion

In this study, we compared user satisfaction and potential complications between SSA and TFA dressings on the hips and found revealed that both dressings provided high user satisfaction. The SSA dressings offered better outcomes in terms of moisture management, dressing stability, and complication rates. The key finding was the difference in moisture under the dressing between the two groups during the 7-day and 14-day follow-ups. A higher occurrence of moisture accumulation was found with the TFA dressing, which could be indicative of inadequate moisture control compared to the SSA dressing. This is clinically significant, as moisture under dressings may contribute to maceration and other complications, or dressing failure [16, 17]. Notably, our study was conducted in a region with ambient temperatures typically ranging from 25 to 35 degrees Celsius and humidity levels around 80%, conditions that could influence dressing moisture in this study. Additionally, there were more incidences of failed dressings and complications with the TFA dressings, supporting the assumption that SSA dressings may be more effective at ensuring dryness in the wound environment while preventing adverse events. These findings also imply that SSA dressings might be more appropriate than TFA dressings for wounds with serous discharge.

There was no significant difference in dressing failure at the 7-day follow-up; however, the dressing failure rate was significantly lower with the SSA dressing at the 14-day follow-up. The dressing failure rate using SSA was lower than that obtained in a previous study (53.1% vs. 67.9%) [13]. The discordance may result from the different locations for wound dressing and characteristics of the enrolled participants. In this study, we applied dressings to the hips of simulated patients, whereas the previous study was performed on the hips or knees of actual patients who underwent hip or knee arthroplasty. Additionally, the number of dressing failures seemed to be similar for both dressing types, in line with the results of a previous study that reported a mean number of dressing changes of 0.28 and 0.27 with SSA and TFA dressings, respectively [14].

The complication rates observed in this study were consistent with those in the previous studies [10, 14]. They reported that 4% of patients who were treated with TFA dressings experienced blistering, irritation, or redness, whereas those who received SSA dressings had no complications [14]. In this study, we also found that the occurrence of complications was greater with TFA dressings; however, a significant difference was detected only at the 14-day follow-up. The findings regarding dressing failure and complication rates emphasize that TFA dressings should not be applied for long periods or > 7 days.

Despite the aforementioned distinctive points, the overall satisfaction and difficulties during the activities of participants were marginally better with SSA dressing but not significantly different when compared to TFA at the follow-up intervals. Our findings align with a previous study that reported slightly better results with SSA compared to TFA regarding general comfort, freedom

of joint movement, and unpleasant sensation [14]. This implies that the factors influencing patient satisfaction are numerous, and can involve other components such as ease of application, discomfort, and pain; hence, even with the differences between the two dressings, the disparity was not significant. Even though the SSA dressing is a soft silicone foam, which can reduce the pain during changing wound dressing, as proposed in the prior studies [14, 18], we did not detect a difference in the degree of pain between the two dressings during application or removal. Owing to the extremely low pain scores and difficulties during activities and the considerably high overall satisfaction when using SSA or TFA dressings, we concluded that both dressings were evenly received by the users, especially when applied to the hip.

To our knowledge, this is the first randomized controlled trial to compare the outcomes between TFA and SSA dressings applied to the bilateral hips; hence, users were able to compare the two dressings directly. However, this study had some limitations. First, the participants were randomly allocated using block-of-four randomization, and the concealed envelopes were opened just before applying the wound dressings. Nevertheless, we did not blind the participants or nurses who applied dressings. This may have caused bias in the satisfaction evaluations. Second, we applied dressings to participants with simulated posterior-approached hip surgical wounds. Thus, the results may not be generalizable to patients who undergo hip surgery using an anterior or lateral approach. Additionally, we did not collect data on the participants' work profiles or daily physical activity levels. However, it is important to note that dressing failure rates may vary depending on the activity levels of postoperative patients. Unlike the active participants in our study, actual postoperative patients typically have a lower level of physical functioning, which could influence these outcomes. Finally, we did not use a validated tool to assess patient satisfaction or difficulty with daily activities. Further randomized controlled trials comparing the outcomes evaluated using validated measurement tools between the two types of dressings in a large number of actual postoperative hip surgery patients would be beneficial to confirm these results and provide more robust evidence.

Conclusions

Both SSA and TFA dressing provided similar minor difficulties in daily activities and high overall satisfaction. This study also revealed preliminary evidence that SSA dressings may offer advantages over TFA dressings in managing posterior-approached hip wound care, particularly in terms of moisture control, reducing complications, and dressing failure rates at the 14-day follow-up. These findings suggest that SSA dressings could be a suitable option for wounds prone to excessive discharge or requiring longer dressing durations, especially in ambient conditions similar to our study setting.

Abbreviations

SSA Silicone-coated self-adhesive absorbent film
TFA Transparent film with absorbent pad

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13018-024-05448-7.

Supplementary Material 1

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Author contributions

All authors contributed to the conception and design of the study, data collection, and data analysis. The first draft of the manuscript was written by Chirathit Anusitviwat. Varah Yuenyongviwat reviewed and edited the manuscript. All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The Institutional Review Board approved the study protocol (REC. 66-488-11-1) and was registered in the Thai Clinical Trials Registry (TCTR20240319010). The procedures were performed in accordance with the ethical principles of the Declaration of Helsinki for medical research involving human participants. Written informed consent was obtained from all participants before their participation in the study.

Consent for publication

Written informed consent was obtained from all individual participants included in this study.

Competing interests

The authors declare no competing interests.

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