Use-Related Root-Cause Analysis of Recurrent Handpiece Failures in Three Shockwave Therapy Devices: A Human Factors Case Report

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Contracted human factors analysis, outpatient men's health clinic, 2022

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Report classification: retrospective case report based on the author's direct involvement. The clinic is not named. Cost figures are scenario estimates, not audited financial statements.

Abstract

In 2022, under contract, I investigated recurrent premature mechanical failures affecting all three radial shockwave therapy devices at an outpatient men's health clinic. The clinic treated approximately 30 patients per day, and over a three-month period each device needed a handpiece repair kit roughly every two days, against an expected service interval of about 60 days. A calendar-day cost model puts repair-kit spending at $54,000 over 90 days compared with an expected $1,800, an excess of $52,200; an operating-day model gives an excess of $34,200 to $37,800. An Ishikawa analysis assessed six groups of possible causes: training and handling, maintenance and rotation, cleaning and disinfection, workload, equipment configuration, and unauthorized barriers. The principal contributing factor was disposable finger cots placed over the handpieces as a between-patient sanitation shortcut, which restricted airflow and increased heat. Staff had adopted the shortcut to save about seven minutes per patient, an efficiency–thoroughness trade-off under heavy scheduling pressure. Removing the finger cots and restoring the manufacturer's cleaning method returned the devices to expected performance. I recommend corrective actions ranked by strength, led by standardizing accessories and cleaning and building cleaning time into the schedule, with monitoring at 30, 60 and 90 days.

Keywords: human factors, medical device reliability, root-cause analysis, Ishikawa diagram, work-as-done, cost of poor quality

Use-Related Root-Cause Analysis of Recurrent Handpiece Failures

How reliably a clinical device performs depends not only on its design but also on how it is used: the task demands placed on staff, local workflows, and the informal adaptations people make to keep a busy schedule moving. Those adaptations are often sensible from the inside, yet they can create technical hazards that no one intended.

This report documents the contracted analysis I carried out in 2022 on recurring handpiece failures across a three-device shockwave therapy fleet at an outpatient men's health clinic, which has since closed. It was written up retrospectively in 2026. Its aims were to identify a shared contributor to the abnormal repair frequency, estimate the material cost of the failures, and recommend corrective actions that preserve appropriate infection control and mechanical reliability. It is written as a retrospective operational case report, not a controlled study. Facility-specific facts come from my direct involvement; published sources support the general maintenance and infection-control requirements but do not independently verify the clinic's event history.

Method

Setting and Inputs

The clinic operated three STORZ MEDICAL D-ACTOR 100 Ultra radial shockwave devices and treated approximately 30 patients per day across them. The inputs to this analysis were: the manufacturer's overhaul guidance of approximately 1,000,000 pulses for the guide tube and projectile (STORZ MEDICAL AG, n.d.); the clinic's working assumption of about 60 days between normal handpiece services per device; an observed repair frequency of roughly once every two days per device; a repair-kit price of $400; and about 90 days of persistent failures before the investigation began. The seven-minute time saving attributed to the sanitation shortcut is a staff estimate per treatment, not a timed measurement.

Root-Cause Method

I used an Ishikawa (fishbone) analysis (Ishikawa, 1990) to structure competing explanations into six groups: operator training and handling; preventive maintenance and device

rotation; cleaning and disinfection; workload and pulse accumulation; equipment configuration; and unauthorized barriers. Because all three devices failed in a similar way, I focused on conditions shared across the fleet rather than treating each breakdown as an isolated component defect. Each branch was assessed against that shared pattern (Table 2).

Financial Estimation

The primary calendar-day model assumes one $400 kit per device every two calendar days over 90 days, compared with one kit per device per 60 days. A secondary operating-day model assumes 60 to 66 clinic operating days within the same 90 calendar days and one failure per two operating days, while keeping the 60-day calendar benchmark. All estimates cover materials only and exclude technician labor, device downtime, disrupted appointments and lost revenue, so they understate the full cost.

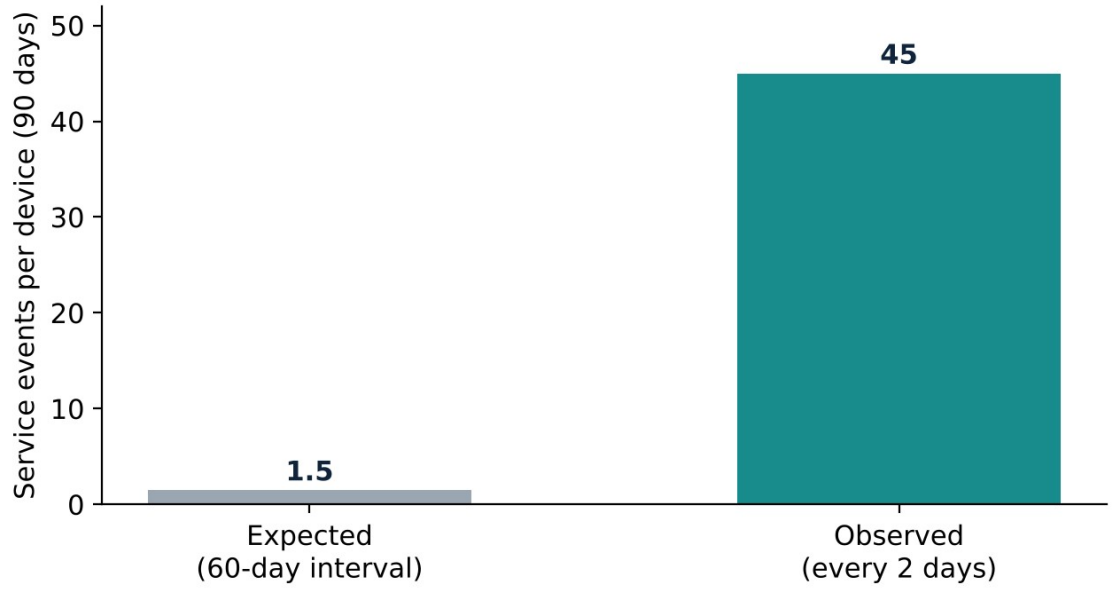
Results

Failure Frequency

Under the calendar-day model, each device had about 45 repair events in 90 days (135 across the fleet), against an expected 1.5 per device (4.5 across the fleet). The repair rate was therefore about 30 times the benchmark, equivalent to a 96.7% shorter interval between service events (Figure 1).

Figure 1

Expected Versus Observed Service Events per Device Over 90 Days



Note. Observed events assume one repair every two calendar days; expected events assume one service per 60 days.

Direct Material Cost

Table 1 and Figure 2 summarize the material cost. The calendar-day model gives $52,200 in excess repair-kit spending across the three devices. If “every two days” referred only to clinic operating days, the excess would be $34,200 to $37,800 (Figure 3). These are scenario estimates, not audited losses.

Table 1

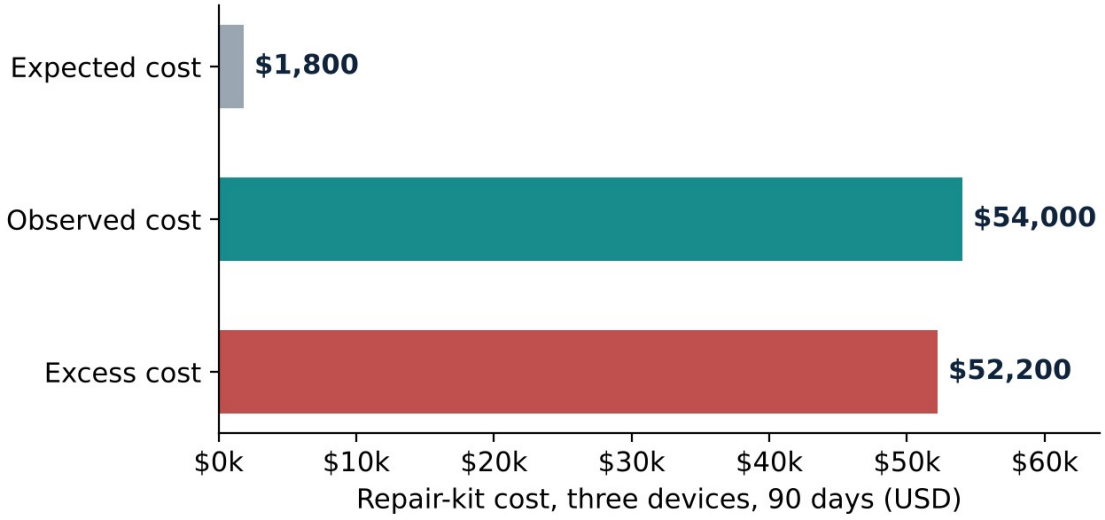
Modeled Repair-Kit Cost Over 90 Calendar Days

Metric	Per device	Three-device fleet
Observed repair events	45	135
Expected service events	1.5	4.5
Observed kit cost	$18,000	$54,000
Expected kit cost	$600	$1,800
Excess material cost	$17,400	$52,200

Note. Calendar-day model. Fractional expected events represent rates, not partial purchases.

Figure 2

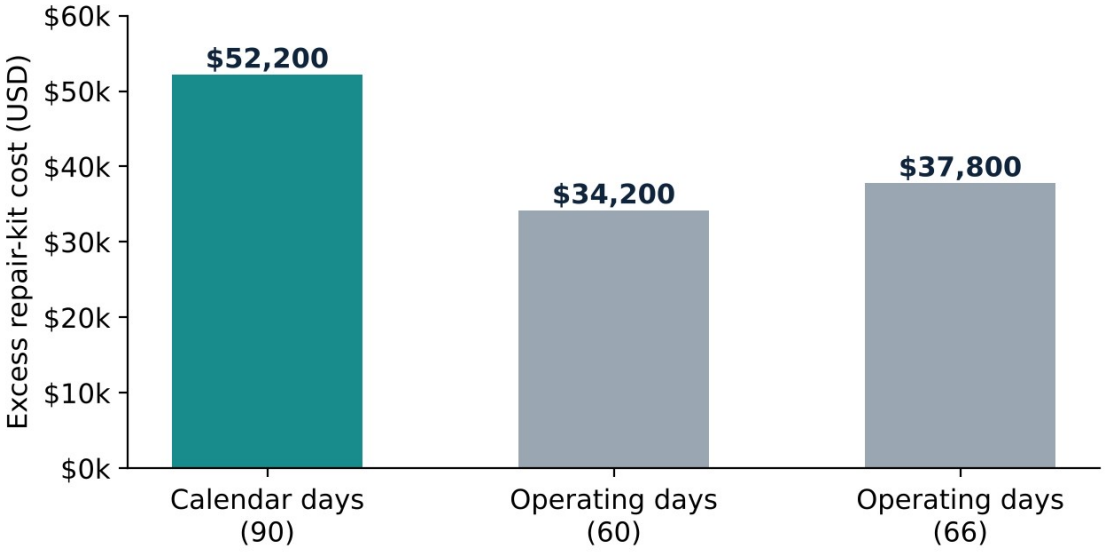
Expected, Observed and Excess Repair-Kit Cost for the Three-Device Fleet



Note. All costs are scenario estimates for 90 calendar days.

Figure 3

Sensitivity of Excess Cost to the Definition of "Every Two Days"



Note. Expected baseline cost held at $1,800 in all three scenarios.

Root-Cause Findings

Table 2 summarizes how each branch of the fishbone was assessed, and Figure 4 shows the full diagram. The one condition present on all three devices that could plausibly shorten component life this sharply was the use of disposable finger cots over the handpieces as protective coverings during treatment. The proposed mechanism is that the coverings obstructed the airflow the handpiece needs and increased heat build-up. I did not have temperature measurements or a controlled comparison, so this is a field-supported causal interpretation rather than a laboratory-validated finding.

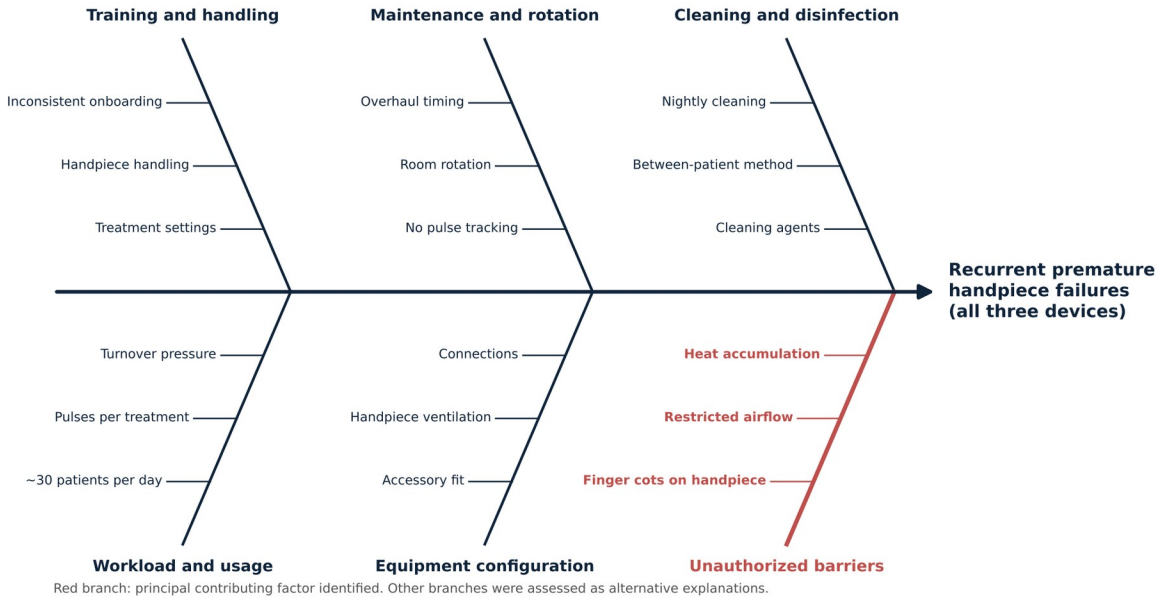
Table 2

Assessment of Fishbone Branches

Branch	Considered	Assessment
Training and handling	Onboarding, handpiece handling, treatment settings	Unlikely to be primary: differences between staff would not readily produce the same failure pattern on all three devices.
Maintenance and rotation	Overhaul timing, rotation between rooms, pulse tracking	Not the failure mechanism, but contributed to late detection: without pulse counts or repair trending, the pattern ran for about 90 days.
Cleaning and disinfection	Nightly cleaning, between-patient method, agents	Linked: the finger-cot shortcut replaced the approved between-patient cleaning.
Workload and usage	~30 patients per day, pulses per treatment, turnover pressure	Created the time pressure behind the shortcut; normal workload alone would not shorten component life about thirtyfold.
Equipment configuration	Accessory fit, handpiece ventilation, connections	Ventilation was the pathway affected once coverings were applied.
Unauthorized barriers	Finger cots over the handpieces	Principal contributing factor: present on all three devices; removal was followed by a return to expected performance.

Figure 4

Ishikawa Cause-and-Effect Analysis of Recurrent Handpiece Failures



Note. The red branch is the principal contributing factor; the other branches were assessed as alternative or contributing explanations.

Outcome

At my recommendation, the clinic removed the finger cots from all three devices and returned to the manufacturer's cleaning and disinfection method between patients. After these changes, the devices returned to their expected performance. The length of post-correction follow-up was not formally documented.

Discussion

Work as Imagined Versus Work as Done

The finger-cot practice is a clear example of the gap between work as imagined and work as done (Hollnagel et al., 2015). On paper, staff cleaned the handpiece between patients with an approved method. In practice, with about 30 patients a day, they covered it instead. The shortcut changed the device's configuration in a way no one anticipated, and the similar failure pattern on

all three devices pointed to a shared practice rather than three faulty components. No patient adverse events were reported, and none should be inferred from this analysis.

Why the Shortcut Made Sense

The shortcut saved an estimated seven minutes per patient. At 30 treatments a day, that is about 210 minutes of cumulative turnover time daily, although not necessarily 3.5 recovered staff hours or additional appointments. From the inside, trading thoroughness for efficiency in this way is locally rational: Hollnagel (2009) describes this efficiency–thoroughness trade-off as a normal feature of work under pressure rather than a failing of individuals. The more useful question is why the schedule left so little room for the approved method that a workaround became the norm. Treating this as staff non-compliance would miss that latent condition, and the shortcut, or another like it, would likely return.

Why the Problem Lasted Three Months

The failures recurred roughly every two days on every device for about 90 days before anyone investigated. Repair kits were absorbed as routine consumables rather than treated as a signal. There was no per-device repair log, no pulse tracking and no threshold that would have triggered a review. This missing feedback loop is an organizational condition in its own right: the system had no way to notice that it was failing.

A Device Usability Question

The handpiece’s dependence on airflow was evidently not apparent to the staff who covered it. Whether the device itself, its labeling or its instructions make this cooling requirement obvious at the point of use is a usability question worth raising with the manufacturer. Use-related failures of this kind are as much a design-and-communication issue as a training issue.

Sanitation Requirements

For noncritical equipment that contacts intact skin, the Centers for Disease Control and Prevention (CDC, 2024) recommends appropriate low-level disinfection, and the manufacturer’s instructions govern the specific method. The D-ACTOR handpiece documentation describes

cleaning and alcohol-based surface disinfection (STORZ MEDICAL AG, n.d.). A finger cot is not a substitute for an approved reprocessing method unless the manufacturer approves it.

Limitations

This is a single-facility retrospective case analysis. When preparing this report I did not have access to the maintenance log, purchase invoices, per-device pulse counts or temperature data, and post-correction follow-up was not formally documented. The cost figures are therefore scenario estimates rather than an accounting total, and the 60-day baseline is an operating assumption; actual overhaul timing should be set from device-specific pulse counts. The improvement after the coverings were removed is consistent with the proposed mechanism, but I cannot fully separate the effect of restored airflow from other practice changes made at the same time.

Conclusion and Corrective Actions

A single, modifiable workflow condition, finger cots used as a sanitation shortcut, was the leading explanation for repeated premature failures across all three devices, at an estimated excess material cost of $34,200 to $52,200 over three months. The shortcut was a reasonable local response to time pressure, and the failures persisted because the clinic had no mechanism to detect them. Table 3 lists the corrective actions, ranked using the action hierarchy from the RCA² framework (National Patient Safety Foundation, 2015): stronger actions change the system so the problem cannot easily recur, while weaker actions depend on people remembering to behave differently.

Table 3

Corrective Actions Ranked by Strength

Strength	Action	Measure of success
Stronger	Remove finger cots from treatment rooms and stock only manufacturer-approved accessories, so the shortcut is no longer available.	No unapproved coverings found on spot checks
Stronger	Standardize one device-specific between-patient cleaning process using manufacturer-approved agents and contact times.	Same process observed across staff and rooms

Strength	Action	Measure of success
Intermediate	Build the time the approved cleaning method needs into the appointment template, so compliance does not depend on staff absorbing it.	Turnover completed within scheduled time
Intermediate	Track pulses per device and trigger overhauls at the manufacturer's interval, not elapsed calendar time.	Overhauls aligned with pulse counts
Intermediate	Keep a repair log (device, date, pulse count, part, cost, downtime) and trigger a root-cause review if any device needs more than one repair kit in 30 days.	Recurrences detected within 30 days
Intermediate	Post a point-of-use cleaning card on each device; ask the manufacturer whether an approved cover exists if faster turnover is needed.	Card present; manufacturer response documented
Weaker	Retrain staff on cleaning, permitted accessories, handpiece airflow and escalation of repeat failures; document completion.	All staff trained
Weaker	Adopt a written policy prohibiting modifications that obstruct ventilation or alter the approved configuration.	Policy issued and acknowledged

Note. Strength categories follow the RCA² action hierarchy (National Patient Safety Foundation, 2015).

I recommend auditing device performance at 30, 60 and 90 days after the changes, comparing failures per device and repair-kit spending with the baseline, and escalating any recurrence. Together, these actions remove the failure-producing workaround, make the approved method practical within the schedule, and add the monitoring needed to show that reliability and cost improvements are real rather than assumed.

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