Technical communications

Safety of anaesthesia breathing circuit connectors

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Conical connectors used in anaesthesia breathing circuits are prone to accidental disconnections. We tested 291 connectors of 15 and 22 mm size and found that most did not comply with dimensional requirements in voluntary standards such as those issued by the Canadian Standards Association (CSA) and the American National Standards Institute (ANSI). However, measurements of disconnecting force showed no strong correlation with dimensional accuracy as determined by the standard gauge tests. When wrung together, metal-to-metal or plastic-to-plastic joints were considerably stronger than metal-to-plastic joints. Wrung joints were much stronger than connections made with a straight push, which showed no marked dependence on the type of material. Our results indicate that improved compliance with dimensional standards as determined by existing gauge tests will not improve connector performance. Rather, what is needed is a performance standard based on practical criteria. Under such a standard, some materials may prove unsuitable for friction-fit connections.

Key words

EQUIPMENT; connectors, standards.

Anaesthesia breathing circuits contain numerous connections made by means of simple cone and socket fittings. They are designed to join easily with a push and to separate with a pull. Most connectors have no locking mechanism.

Although conical fittings are simple and convenient, they are susceptible to accidental disconnection which, if not detected in time, can result in severe trauma or death of the patient. In many operations, especially head and neck surgery, the practice of draping the entire patient makes it more likely that disconnections near the patient end of the breathing circuit will not be noticed. A study by Cooper *et al.*¹ of 359 anaesthesia incidents showed breathing circuit disconnections to be the single most frequent occurrence (7.5 per cent). A recent survey of Canadian anaesthetists² showed that most of them experience several disconnections per year. Such avoidable accidents are a known cause of death.

Over the years the design of conical fittings has been standardized by consensus. The dimensions and tolerances of the commonest sizes, nominal 15 mm and nominal 22 mm, are now specified by several voluntary standards.³⁻¹⁰ The ones most commonly referred to are those of the American National Standards Institute (ANSI),^{3,4} the Canadian Standards Institute (ANSI),⁵ and the British Standards Institution (BSI).⁶ With a few minor differences, these standards are compatible in their dimensional requirements for taper, diameter and length. Figure 1 shows the design of male and female conical connectors and the Table lists the standard dimensions. Compliance with the standards is tested by mating connectors with a ring or

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Standard reference number	Size	Connector dimensions as shown in Figure 1				
		A	B	C	D	S
3, 4, 5, 6, 7, 8, 9, 10	15	15.47 ± 0.04 Note 1	16 min Note 2	14.5 + 0.5 - 0 Notes 1, 3	10.0	
4, 6, 7, 8, 9, 10	22	22.37 ± 0.04 Note 1	21 min	19.5 + 0.5 -0 Notes 1, 4	15.0	26 min Note 5

TABLE Standard dimensions for conical connectors (mm)

NOTES

1. Ref. 6 does not specify tolerances.

2. Refs. 4 and 5 do not specify dimension B.

3. Ref. 6 requires C = 16 mm nominal. Ref. 8 requires 14.5 mm if connector has a recess behind tapered portion, 16 mm with shoulder.

4. Refs. 7, 8, 9 and 10 require 19.5 mm if connector has recess behind tapered portion, 21 mm with shoulder.

5. Refs. 4 and 6 do not specify dimension S.

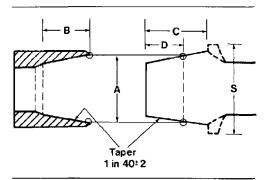


FIGURE 1 Design of standard conical connectors.

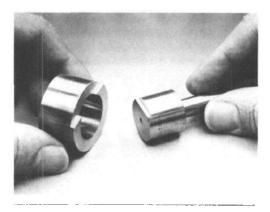


FIGURE 2 Ring and plug gauges for measuring dimensions of connectors according to ANSI specifications.

plug gauge whose dimensions are specified in the standards. Figure 2 shows a pair of ring and plug gauges made to the ANSI specifications. The connector must mate securely without rocking and the penetration distance must lie between limits defined by steps machined in the gauge; that is, the connector must not bottom or shoulder.

Many plastic and rubber connectors do not comply with standard dimensions. Shaw *et al.*¹¹ conducted a study in two Scottish hospitals where they measured 134 connectors for compliance with BS 3849. They found that most were far outside the tolerances, even when marked with the BSI standard number.

In this paper we discuss existing voluntary standards for conical fittings, the degree of compliance with these standards, and our laboratory evaluations of the performance of conical fittings now on the market. We also suggest several possible ways of improving the safety of conical connectors.

Methods and results

We tested a total of 291 connectors of 15 and 22 mm size for compliance with the ANSI ring and plug gauges. The connectors were from ten different manufacturers and made of various materials. Five of the ten manufacturers claim compliance with one of the standards. On the basis of these tests, we categorized the diameter of each connector as acceptable, too large or too small. Forty-six per cent of the connectors were acceptable, 29 per cent too

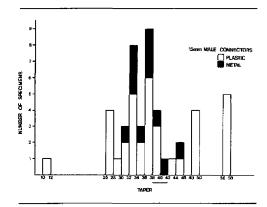


FIGURE 3 Measured taper of 15 mm plastic and metal male connectors. Bracket at 40 ± 2 indicates tolerance allowed by standards: a taper range of 1 in 38 to 1 in 42.

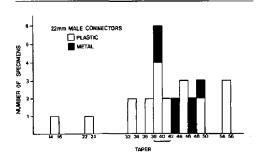


FIGURE 4 Measured taper of 22 mm plastic and metal male connectors. Bracket at 40 ± 2 indicates tolerance allowed by standards: a taper range of 1 in 38 to 1 in 42.

large, and 25 per cent too small. Twenty-one per cent of the male connectors were shorter than the minimum specified by the standards.

Ideally, a pair of connectors ought to make contact over the entire surface of the overlapping cones. Taper mismatches will result in a ring contact, and deviations from roundness will result in line or point contact, although deformable materials will compensate to some extent for dimensional inaccuracies. We measured the taper of male connectors for comparison with the standard requirement of 1 in 40 \pm 2 (i.e., a change in diameter of one part in a length of 40 \pm 2 parts). Figure 3 shows a histogram of the measured tapers for 15 mm male connectors. The measured values ranged from 1 in 10 \pm 1.5 to 1 in 58 \pm 1.5. Only 11

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per cent (five out of 46 samples) had a taper within specification. The results for 22 mm connectors are shown in Figure 4. The tapers ranged from one in 14 to one in 56 with only 31 per cent (eight out of 26 samples) within specification. Both plastic and metal connectors appeared to be equally inaccurate.

One might expect metal connectors to be more accurately sized than plastic ones. Figure 3 shows that although the observed range of tapers was smaller for metal components, only two of eleven 15 mm metal connectors had a taper within the standard range. The tapers varied from 1 in 30 to 1 in 45. Among the 22 mm connectors (Figure 4) only two out of seven had a taper within the standard range. Some pairs of metal connectors were so mismatched that they fell apart under their own weight!

In order to see the degree to which diameter accuracy affects the strength of the joint, we measured disconnecting forces for pairs of connectors classed according to their size as measured by the gauge tests. The connectors were joined with a force of 8 kg without twisting, and the disconnecting force was measured and recorded on a tensile test machine.

Figure 5 shows the results for connectors grouped according to their measured size. A plus sign indicates an oversized connector, a minus sign

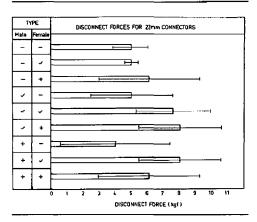


FIGURE 5 Disconnect forces for 22 mm connectors joined with a straight push of 8 kg. Results grouped according to measured size. "+" indicates connectors with greater than specified diameter as determined by ring and plug gauge tests; "-" indicates undersized diameter; " \checkmark " indicates diameter within tolerance.

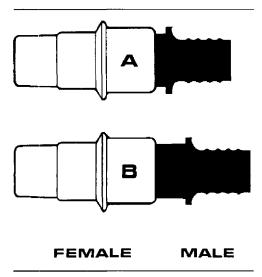


FIGURE 6 Typical effect of shrinkage caused by autoclaving a plastic female connector. A: before. B: after. Note reduction in insertion distance due to shrinkage.

indicates undersize and a check mark indicates a connector within the gauge tolerances. For example, the top line (-,-) shows the measured forces required to disconnect undersized male connectors from undersized female connectors.

We found no strong correlation between the size accuracy of connectors and the mean disconnecting force, which was roughly 6 kg. In each group the standard deviation was large compared to the reproducibility of the measurement for a given pair of connectors, indicating real variations among the connectors. It seems probable that these variations arise from taper and roundness errors and differences in materials. We found some connectors which were so far out of tolerance that they bottomed or shouldered. Of course, in these cases the disconnecting forces were markedly lower, averaging 2 or 3 kg.

The cost of disposable anaesthetic components has prompted some users to sterilize and re-use connectors designated by the manufacturer as single use items. Although cold chemical sterilization may not affect most plastics, autoclaving causes noticeable shrinkage unless the component is made of teflon or pre-shrunk material. We measured the insertion depths into the standard ring and plug gauges of 40 connectors before and after autoclaving. The shrinkage resulted in an average change in the insertion distance of 7 mm, or about 50 per cent of the tapered length of a connector. A typical result is shown in Figure 6.

It has been suggested that connectors made of the same material form stronger joints than ones made of different materials. To investigate this question, we measured disconnecting forces as a function of the connecting forces for different pairs of 22 mm connectors and for the standard 22 mm ring and plug gauges themselves. The components were joined on a press equipped with a force scale and separated on a tensile test machine. Two sets of measurements were taken — one in which the connectors were joined with a straight push, and one in which they were wrung together with a twist as the force was applied.

The results, shown in Figure 7, reveal several important features. First, joints which are wrung together are much stronger than those made with a straight push. In fact, the disconnecting forces for wrung joints are typically twice as large as the connecting forces. For joints made with a straight push, the disconnecting forces are less than the connecting forces.

The performance of the ring and plug gauges can be regarded as representing the best which can be expected for metal conical fittings since they are made of hardened steel precisely machined to very close tolerances.

When the connectors were wrung together (a procedure which is common practice in actual use), metal-metal and plastic-plastic joints were considerably stronger than metal-plastic joints and were, on average, comparable to gauge joints although the scatter in the disconnecting forces was much greater. When made without twisting, all joints, regardless of materials, were roughly equivalent but much weaker than wrung joints.

Discussion

Present standards for connectors are design, not performance standards; they specify dimensions and tolerances but not joining and separation forces. A major assumption implicit to all design standards is that the design specifications are both necessary and sufficient to ensure the desired performance. The gauges are useful primarily for checking the diameter of the connectors, since rocking is at best only a rough qualitative indication of taper mis-

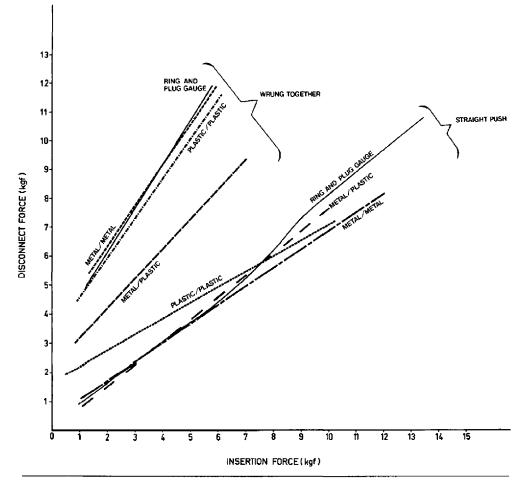


FIGURE 7 Variation of disconnect force with insertion force for 22 mm connectors and 22 mm ring and plug gauges.

match or lack of roundness. However, errors in taper and roundness are probably more important than variations in diameter as a cause of poor connections.

There are discrepancies between the width of the gauge steps and the dimensional tolerances specified for the connectors. Presumably, the step width is meant to accommodate the full range of dimensions allowed by the tolerances in the connector standards. However, it can be shown that the steps are not wide enough to pass connectors with the extreme values of diameter, even if their taper is exactly the nominal value. To pass a connector with the extreme values of diameter and taper would require even wider steps. Additional confusion has arisen because the diagram of the 15 mm test gauges in ANSI standard Z79.2 contains an error in the width of one of the steps. A corrected drawing is available from ANSI, but is not always included with new copies of the standard. The ANSI, CSA and ISO standards are currently under review by their respective committees with the aim of removing errors and inconsistencies.

Several possible factors may explain the large deviations from standard taper among plastic connectors. One is that plastic parts are hard to manufacture to strict tolerances because of shrinkage during moulding. Another is that some plastic connectors are made and sold by firms which are not primarily medical device manufacturers and are unaware of applicable standards. A third reason is that the connector dimensions were standardized at a time when practically all components were metal. With the introduction of various kinds of plastic, manufacturers discovered that some plastic connectors with the prescribed taper did not mate securely with metal fittings and increased the taper of the plastic connectors to obtain a better joint! However, like the brands surveyed by Shaw *et al.*¹¹ some may continue to claim conformity with the standards.

There are at present no recommended values for disconnecting forces, although the CSA, ANSI and ISO committees are considering the inclusion of such provisions in their revised standards. Obviously, for a friction fit connection, an upper limit should apply as well as a lower one, since too large a disconnecting force could be hazardous in emergency situations where components must be separated quickly. Except for metal components, it may be difficult to ensure a predictable disconnecting force by specifying dimensional tolerances only. Even then, the disconnecting force will depend on the joining force and the degree of twist, neither of which can be accurately controlled in use.

An alternate solution would be to make a connector with a latch or locking mechanism which would require minimum effort to operate. Such connectors exist on the market but are not widely used. The connectors themselves are basically the standard tapered friction fittings with the addition of a locking collar. Use of the collar is optional.

Another strategy adopted by some manufacturers is to provide hooks on the connector which allow the user to apply rubber bands to hold the joint together. This method was endorsed in an ANSI draft standard¹² for anti-disconnect mechanisms which was later withdrawn, and few anaesthetists seem to use it. However, many routinely use adhesive tape to secure connections, even though this procedure is time-consuming and messy. Furthermore, joints sometimes separate under the tape, resulting in large leaks which are hard to locate. Frequently, the connectors cannot be rejoined without removing the tape first.

Discussions in ANSI standards committees revealed considerable reluctance in the US to support the introduction of locking connectors. Many felt that a connector which can only be joined by locking would be slow and awkward to use. On the other hand, a connector with an optional lock was seen to have adverse implications on legal liability in case of a disconnect: an anaesthetist who had chosen not to use the lock could be charged with failure to take all reasonable safety precautions. These views were not apparent in the survey of members of the Canadian Anaesthetists' Society.² The commonest reason given for not using anti-disconnect mechanisms was that they were not available (although, as noted above, this is not the case).

The CAS members expressed some reservations about locking the tracheal tube connector. Here a case can be made in favour of a non-locking connection to act as a safety release to prevent accidental extubation. There are no data to determine whether a securely joined tracheal connection would separate before the tube was pulled from the trachea. Furthermore, the CAS survey showed that 54 per cent of respondents regularly tape the tracheal connection, thereby defeating the safetyrelease feature.

In addition to valid reservations about locking connectors, we have also encountered some irrational prejudices. A few users have expressed the fear that a locked connection could not act as a pressure relief valve in case of accidental overpressures in the patient circuit. In fact, a 22 mm conical fitting, even with a low disconnecting force of 6 kg, would not separate until internal gas pressures reached about 1500 cm of water. For a 15 mm connector the pressure would be roughly twice as great. Lung injury occurs at pressures of 60–100 cm of water.

Conclusions

Our results have shown that the large majority of connectors currently on the market do not meet the dimensional specifications in the relevant standards. However, it is not evident that compliance with current specifications as determined by gauge tests would improve the reliability of the connections since we found little correlation between size and disconnecting force. Errors in taper and roundness, which are not easily detected by the gauge tests prescribed in the standards, may be more important than variations in size. Furthermore, the experience of some makers of plastic connectors suggests the possibility that a secure joint between a

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deformable plastic and metal may even require a dimensional mismatch. If this is so, then improved dimensional accuracy of plastic connectors may even degrade performance.

Because of large shrinkage effects, plastic connectors should not be autoclaved unless they are made of heat-resistant materials.

Wherever possible, joints should be wrung together since this procedure can easily double the strength of the connection.

Locking connectors, though available on the Canadian market, are not widely used. The fact that most anaesthetists tape connector joints indicates a real need for safe and convenient locking mechanisms. Since a properly mated conventional conical joint can not function as a gas pressure relief valve, locking the joint would not increase the chances of lung damage due to accidental overpressures.

We believe that current standards efforts should be directed at ensuring adequate performance rather than dimensional accuracy. This effort will require performance criteria based on reasonable connection and disconnection forces. The great variety of materials now used for connectors will pose problems in devising appropriate test methods. It may be that some materials cannot make reliable connections by means of the conventional conical friction fit. If this is so, it may be necessary to explore other connector designs or locking accessories to improve the safety of these crucial components in the life support system.

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Résumé

Les raccords coniques des circuits de ventilation utilisés en anesthésie sont sujets à des séparations accidentelles. L'essai de 291 circuits a permis de constater que les dimensions de la plupart n'étaient pas conformes aux recommandations de l'Association canadienne de normalisation et de l'American National Standard Institute. Cependant, on n'a observé aucune relation marquée entre les mesures de la force nécessaire pour disjoindre les raccords et la précision des dimensions calculée à l'aide d'un calibre normalisé. On a constaté que, lorsqu'on les serrait, les joints de matériaux différents (métal et plastique) étaient considérablement plus faibles que ceux fabriqués avec le même matériau (métal et métal ou plastique et plastique). Indépendamment des matériaux utilisés, les raccords des pièces qui s'emboîtaient seulement étaient beaucoup plus faibles que les joints serrés. Les résultats de nos recherches indiquent qu'une meilleure conformité des dimensions aux normes - déterminée grâce aux méthodes d'étalonnage actuelles n'améliorera pas l'efficacité des raccords. Il faudrait plutôt une norme de performance reposant sur un critère d'ordre pratique. Une telle norme permettrait peut-être d'établir que certains matériaux ne conviennent pas à des raccords ajustés soumis à des frottements.

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