Original Article

Changes in hardness and resilience of i-gel^{TM} cuffs with temperature: a benchtop study

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Summary

The i-gel^{TM} is a supraglottic airway with a gel-like thermoplastic cuff. It has been suggested that the seal around the larynx improves following insertion. Perhaps the most intuitive hypothesis proposed for this is that cuff softening occurs during warming from ambient to body temperature. We investigated this using a food industry texture analyser over a wide temperature range. Size 2 and 3 i-gels were secured to a platform within a temperature-controlled water bath, which was in turn mounted on a texture analyser test stand. Both water and i-gel cuff temperatures were recorded. A spherical probe was advanced 4 mm into the surface of each i-gel at a rate of 1 mm.s^{-1}, then retracted at the same rate while the upward pressure on the probe was recorded. Three runs made at each of the 11 temperatures (10 °C to 60 °C, 5 °C increments) gave 105,864 data points, from which values for hardness (the peak force on the probe at maximum indentation), and resilience (the rate at which the material recovers its original shape) were calculated. Over 10 to 60 °C, the smallest hardness value expressed as a proportion of the largest was 88.2% and 89.8% for size 2 and 3 i-gels, respectively, and for resilience these were 92.8% and 86.2%, respectively. Over room temperature to body temperature range (21–37.4 °C), hardness decreased by 3.15% and increased by 0.47% for i-gel sizes 2 and 3, respectively, whereas resilience values decreased by 1.85% and 2.68%, respectively. Cuff hardness and resilience did generally reduce with warming, but the effect was minimal over temperature ranges that may be encountered during clinical use.

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Accepted: 6 March 2018
Keywords: airway management; i-Gel; supraglottic airway device

Introduction

The i-gel^{TM} (Intersurgical, Wokingham, UK) is a single-use supraglottic airway that was introduced into clinical practice in the UK in 2007. It has a wide flat stem that acts as a bite block and reduces rotational malposition, an oesophageal vent and a soft non-inflatable cuff made of a gel-like thermoplastic elastomer (styrene-ethylene-butadiene-styrene).

Some authors have observed that the sealing pressure of the gel-like cuff against the tissues of the larynx improves over time, compared with the situation immediately following initial insertion [1–13]. One

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mechanism proposed to explain this is that the material from which the i-gel cuff is manufactured may soften with warming, thus improving conformity to laryngeal anatomy as it approaches body temperature [3, 5, 6, 8–10]. This view has also been expressed on internet nurse anaesthesia and first-aid forums [14, 15].

By definition, a thermoplastic material is a substance that becomes plastic or softens on heating and hardens on cooling, a property that facilitates manufacture by injection moulding. It may be that use of the word thermoplastic to classify this cuff material has been responsible for the assumption that the cuff softens as it warms up to body temperature postinsertion. It also appears to have at least been suggested (as a common misconception) that the polymer of the cuff might physically expand on heating, and it is this effect (as opposed to softening) that may improve sealing properties after insertion [15].

Against this background, previous investigators have examined the effect of warming i-gels to 42 °C for 30 min or keeping them at room temperature before insertion. The pre-warmed i-gels showed smaller leak volumes 30 s after initiation of mechanical ventilation [16], although in another study by the same authors this finding was not replicated in non-paralysed, sedated patients [17].

In order to investigate this further, we felt that it would be logical to examine whether the i-gel cuff material softens with increasing temperature. Texture analysers are used in engineering to test properties of materials, and variants of these are also used in the food industry for testing properties of foodstuffs, including gels. We used a texture analyser and a purpose-built rig to evaluate the properties of i-gel cuffs over clinical temperature ranges.

Methods

Opinion was sought from our Regional Ethics Committee, and it was decided that formal approval was not required for this type of investigation.

Two different sizes of i-gel (2 and 3) were tested. An insulated laboratory water bath containing a thermostatically controlled heating element and water recirculation pump (Tempette Junior, Techne, Minneapolis, MN, USA) were used to control the temperature of i-gels under test. A custom-made platform was fixed beneath the surface of the water to support the lateral edge of the i-gel cuff under test. This was in full contact with the upper surface of the platform, with no space between these two surfaces (Fig. 1). This water bath was mounted in its entirety on the base platform of a food texture analyser machine (TA/XTPlus, Stable Microsystems, Godalming, Surrey, UK).

The sensor tip of a previously calibrated digital thermometer (Model F338, Hygiplas, Avonmouth, UK), mounted at a depth of 4 cm below the surface of the water was used to continuously measure water temperature during testing. The 4.8 mm diameter tip of a flexible temperature sensor probe (YSI400 Series, Harvard Apparatus, Cambourne, Cambridge, UK) was inserted to a depth of 8 mm into the distal oesophageal vent port of the i-gel, forming a close fit and attached to a temperature monitor (TM-200D, SIMS, Timperley, Altrincham, UK) in order to measure the temperature of the i-gel cuff material.

During each experimental series of measurements, the food texture analyser machine was controlled by

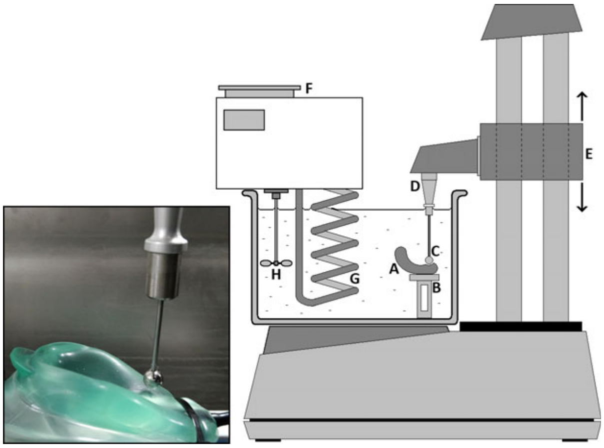

Figure 1 Apparatus (inset: photograph of measurement in progress). The i-gel under test (A) is mounted on a metal platform (B) within a water bath. The circular probe (C) of the texture analyser machine indents the surface of the i-gel cuff and then reverses direction. During this manoeuvre the force acting on the probe is measured by a force transducer (D) mounted on a sliding arm (E) which moves up and down under computer control. An adjustable temperature control unit (F) maintains the water temperature via a heater coil (G) and stirrer (H). Thermometers for measurement of water temperature and i-gel cuff temperature are not shown.

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an attached computer running dedicated software (Exponent, Stable Microsystems, Godalming, Surrey, UK). This machine was fitted with a spherical 7-mm diameter stainless steel test probe, which was set to advance slowly towards the upward facing surface of the i-gel cuff, compress a portion of the cuff material slightly in a repeatable manner and then reverse direction. While carrying out this automatic manoeuvre, a force transducer above the test probe (onto which the test probe was mounted) measured the upwards force acting on the probe as it was pushed into, or removed from, the surface of the i-gel material.

At the start of each test run the probe was programmed to advance towards the surface of the i-gel at 1.5 mm per second. On contact with the i-gel surface (defined as a measured upward force on the probe of 5 g), the computer commenced recording of: the upward force on the probe; the position of the probe along the vertical axis; and the time at 5-ms intervals. For clarity, although the SI derived unit for force is the Newton, the texture analyser recorded upward force on the probe as the equivalent in grams (equivalent to 0.00980665 Newton). After initial contact with the surface, the probe thereafter advanced to a depth of 4 mm into the surface of the i-gel, deforming it slightly at a rate of 1 mm per second. It then reversed direction, moving upwards again and withdrawing the probe from the i-gel surface at the same rate. Once the upward force on the probe (generated by contact with the i-gel) fell below 5 g, the data recording stopped. For each run, a graph of vertical distance on the x-axis vs. force on the y-axis produced an upward curve as the probe pushed into the surface, producing a maximum value when at the full depth of 4 mm, followed by a downward curve as the probe slowly withdrew from the i-gel surface. These test settings were selected from the texture analysis software package as appropriate for the testing of gels.

The temperature of the water bath was adjusted so that measurements of the properties of the i-gel could be made at 11 fixed temperatures (isotherms) ranging from 10 to 60 °C in 5 °C increments. At the lower end of this range ice was added to the water bath to achieve the desired temperature. The target i-gel temperature was considered to have been reached when the sensor within the i-gel measured a temperature that was within ± 0.3° of the target value.

For each size of i-gel (2 and 3), 1604 datasets of elapsed time, the distance moved by probe from the initial point of contact with the surface of the i-gel and the force measurements made as the probe moved, were collected at a sampling frequency of 200 Hz. This data was saved in individual comma-delimited (.csv) spreadsheet files. At each of the 11 temperature isotherms 10–60 °C in 5 °C increments), three sets of texture measurements were made and the mean values used for subsequent analysis. All data were successfully collected with no drop-outs, a total of 105,864 measurements. Initial data manipulation was performed using Microsoft Excel (Microsoft, Redmond, WA, USA) and curve-plotting and analysis was performed using bespoke routines written by an author (DW) in the scientific programming language Python (www.python.com). The following indices were calculated from the data: hardness; hysteresis loop area; and resilience (Fig. 2).

Hardness is the peak force exerted on the transducer, and occurs at maximal descent of the probe (with maximum indentation of the material under test).

Hysteresis (from the Greek 'lagging behind') is a term for a phenomenon in physical and social sciences characterised by non-linear behaviour, in which the output of a system is dependent, not only on the value of the input but also on the history of previous inputs. In mechanics, elastic hysteresis occurs during loading and unloading of deformable substances, resulting in a loop on a force vs. extension plot. The area enclosed by the loop represents energy dissipated due to material internal friction. This concept is familiar to anaesthetists in the form of pressure-volume loops of lung compliance; the additional energy required to recruit alveoli during inspiration results in characteristic hysteresis loops. In this study, plots of force vs. distance of penetration of the probe tip into the i-gel surface produced a series of hysteresis loops (one loop at each temperature) for each i-gel studied. An example is shown in Fig. 2a. Elastic hysteresis is also dependant on rate of deformation; rapid loading and unloading causes greater hysteresis [18]. In this investigation, the rate of loading and unloading was the same in each experimental run, that is, the probe moved into and out of the surface of the material at 1 mm.s^{-1}. This leads on to the engineering concept of resilience, which is the more appropriate term in the context of materials testing.

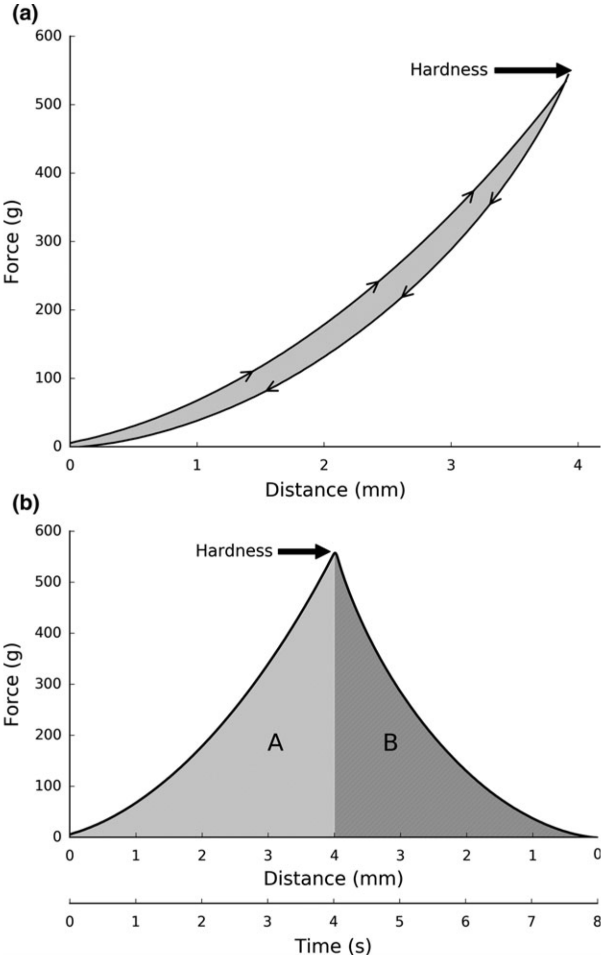

Figure 2 Method of calculation of metrics (for compression and expansion of a size 2 i-gel at 10 °C): (a) force–distance plot showing hysteresis loop: upper curve (right-pointing arrows) and lower curve (left-pointing arrows) indicate relationship during compression and expansion, respectively. Hardness (peak force, g) and energy loss (area enclosed by hysteresis loop; shaded, g.mm) are shown. (b) force–time plot of the same data as a), showing hardness (peak force, g); and resilience (dimensionless quantity), defined as upstroke energy divided by downstroke energy (area B/area A).

Resilience is a dimensionless quantity which describes how rapidly a substance returns to its original form following compression. It is calculated by dividing the upstroke energy by the downstroke energy, given by the areas under the curve of force vs. time. An example is shown in Fig. 2b. In this study, areas under the curve were measured using an implementation of Simpson's Method for definite integrals.

Data were visualised as plots of force on the y-axis against elapsed time on the x-axis. As the probe advanced and retracted at 1mm per second, distance travelled was also displayed along the x-axis. The high density and overlap of the curves necessitated the use of colour (rather than line style) to differentiate isotherms in the plots. We, therefore, applied 'colour-blind safe' design principles and colour palettes [19] and checked the results for legibility using colour-blind simulator software (www.vischeck.com) [20].

Results

Reproducibility was very high, with very small standard deviations within each set of three measurements made at each isotherm. Mean values were used for analysis.

The results for hardness and resilience at each isotherm are shown in Table 1. The curves of force vs. distance of penetration into the i-gel cuff surface at each isotherm for each size of i-gel are shown in Figs. 3 and 4, respectively. It can be seen that the peak force on the probe (when at its maximum 4 mm penetration into the cuff surface, reflecting cuff hardness) did reduce as temperature increased. Over the temperature range studied (10–60 °C), the smallest value for hardness expressed as a percentage of the largest hardness value was 88.2% and 89.8% for size 2 and 3 i-gels, respectively.

For both sizes of i-gel, as the temperature was increased the resilience (reflecting how rapidly a substance regains its original height following compression) decreased, although this was non-linear. Over the temperature range studied (10–60 °C), the smallest value for resilience expressed as a percentage of the largest resilience value was 92.8% and 86.2% for size 2 and 3 i-gels, respectively.

The results in Table 1 were plotted (Figs. 5 and 6) and also modelled as third-degree polynomial curves (using bespoke code written in Python) in order to accurately interpolate values of hardness and resilience at ambient temperatures of 21.0 °C (nominal room temperature) and 37.4 °C (nominal body temperature). By extrapolation from these curves, the hardness of the size 2 i-gel decreased from 545.76 to 528.59 g (a change of − 3.15%), and that of the size 3 i-gel increased from 691.09 to 694.37 g (+ 0.47%). The resilience of the size 2 i-gel decreased from 0.83 to 0.82

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Table 1 Hardness and resilience for size 2 and size 3 i-gels at 11 isotherms, 10–60 °C in 5 °C increments.

	Size 2 i-gel		Size 3 i-gel	
Temperature (°C)	**Hardness (peak force; g)**	**Resilience**	**Hardness (peak force; g)**	**Resilience**
10	556.45	0.82	688.89	0.93
15	549.93	0.83	693.58	0.94
20	547.28	0.83	697.26	0.93
25	542.19	0.83	699.81	0.93
30	537.80	0.83	697.74	0.92
35	530.86	0.82	702.52	0.91
40	524.01	0.82	696.45	0.90
45	519.09	0.80	687.13	0.88
50	511.34	0.79	674.48	0.87
55	499.51	0.77	657.05	0.84
60	490.64	0.77	630.68	0.81

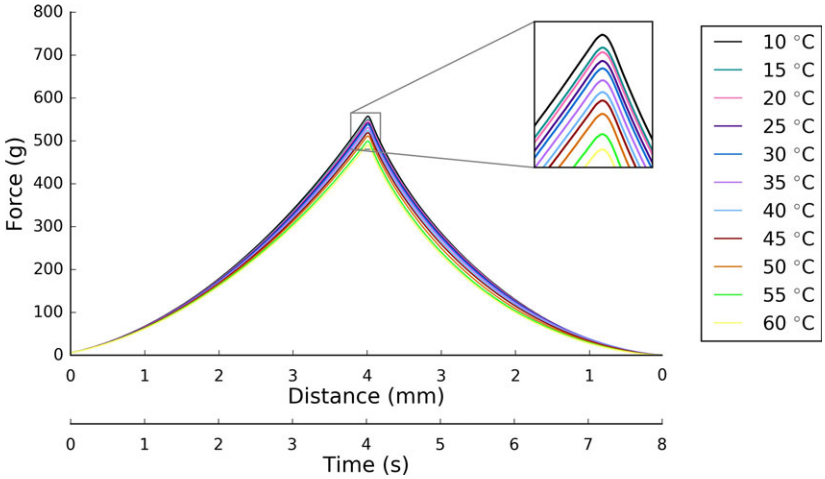

Figure 3 Size 2 i-gel Force (g, y-axis) against distance (mm, primary x-axis) and time (s, secondary x-axis) for isotherms 10–60 °C in 5 °C increments (each isotherm is the mean of three sets of readings).

(− 1.85%), and that of the size 3 i-gel decreased from 0.93 to 0.91 (− 2.68%).

To reflect a more extreme situation of a wider temperature range (as in pre-hospital use on a cold day where a paramedic inserts an i-gel stored at 10 °C into a pharynx at normal body temperature), hardness of the size 2 i-gel decreased from 556.45 to 528.59 g (− 5.01%), and that of the size 3 i-gel increased from 688.89 to 694.37 g (+ 0.80%). The resilience of the size 2 i-gel decreased from 0.820 to 0.817 (− 0.31%), and that of the size 3 decreased from 0.910 to 0.907 (− 2.52%).

Discussion

I-gels are made from a thermoplastic elastomer, which implies that this type of material will soften on heating, and it seem very reasonable to assume that i-gels will soften as they warm to body temperature. However, these elastomers typically have a melting point above 200 °C, and the key question is whether there is softening of the cuff in the temperature ranges encountered in clinical use.

By mounting the i-gel in a fixed position within a water bath and mounting the water bath on a test stand, it was possible to repeat each test on the same part of the i-gel without any accidental movement. Movement would have presented a different part of the i-gel to the test probe (possibly of a different thickness) making any resulting data difficult to interpret. The probe advanced and retracted at a constant rate, causing the same rate of deformation of the i-gel cuff in each case. The modest test depth of 4 mm was

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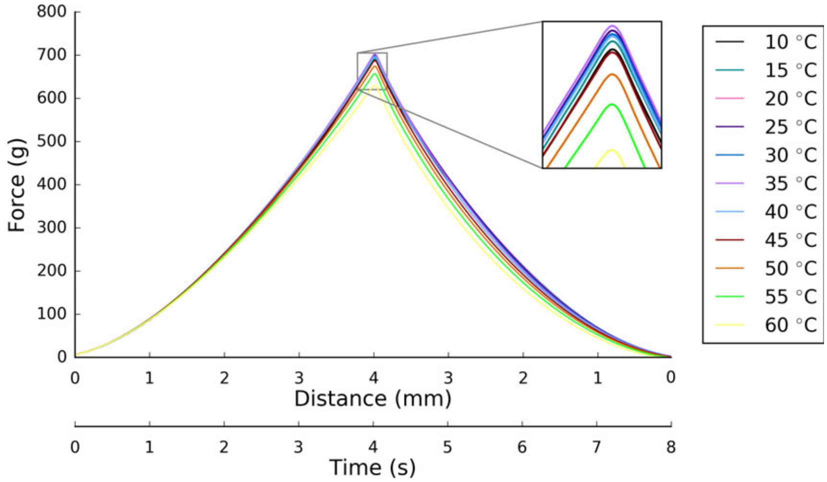

Figure 4 Size 3 i-gel Force (g, y-axis) vs. distance (primary x-axis) and time (secondary x-axis) for isotherms at 10–60 °C in 5 °C increments (each isotherm is the mean of three sets of readings).

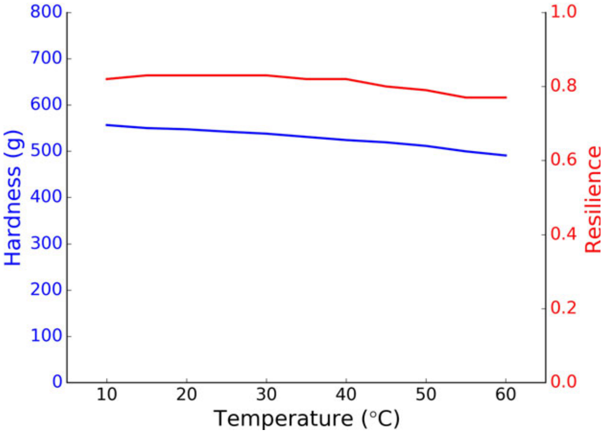

Figure 5 Trend plot of hardness (peak force) and resilience of the size 2 i-gel cuff with increasing temperature.

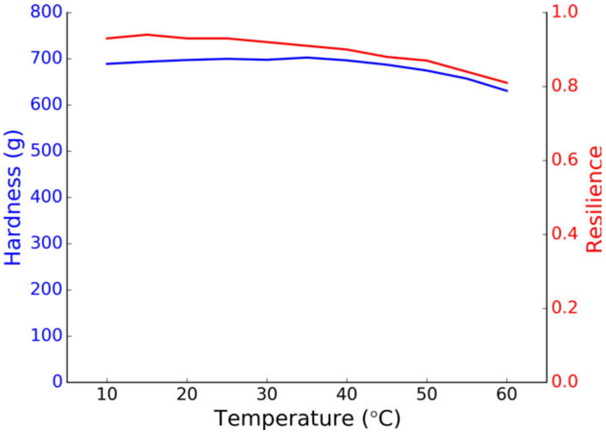

Figure 6 Trend plot of hardness (peak force) and resilience of the size 3 i-gel cuff with increasing temperature.

selected to prevent damage to the cuff surface from the testing itself. The high level of reproducibility of results for the three measurements at each temperature provides evidence that damage did not occur during testing.

The peak values for hardness and resilience were slightly smaller with the size 2 i-gel compared with size 3. This may be a consequence of the measured force being a function of the thickness and/or volume of material tested under the chosen contact point of the probe for each of these i-gels. All curves showed similar peak force or hardness, although there was a trend for hardness to decrease slightly with increasing temperature. Resilience also decreased slightly with increasing temperature. This can be thought of as a slightly slower rate of return to the original shape for the i-gel under test. However, over the range of temperatures expected in clinical use, hardness changed by only − 3.15% and 0.47% for size 2 and 3 i-gels, respectively, whereas their resilience values changed by − 1.85% and − 2.68%. Even when considering a more extreme hypothetical pre-hospital use scenario on a cold day with an i-gel at 10 °C inserted into a patient at 37.4 °C, hardness changed by only − 5.01% and 0.8% for size 2 and 3 i-gels, respectively, with their resilience values changing by − 0.31% and − 2.52%.

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These are small changes, and cannot explain observed differences in cuff seal pressure over time.

Although we did not test physical expansion of the cuff with temperature (as opposed to cuff softening) it is noteworthy that the coefficient of linear expansion (fractional change in length per °C) of styrene–ethylene–butadiene–styrene is 16×10^{-5}, and so physical expansion in size with warming to body temperature is also unlikely to be a mechanism by which the seal might improve over time [21]. Other possible alternative hypotheses for this change could be: interstitial fluid redistributes in the areas in direct contact with the cuff, so improving the seal slightly over time; an interaction between saliva and the cuff material alters its properties and migration of i-gel after insertion into a position of better fit.

In conclusion, we have found that both the hardness and resilience do generally decrease with warming. However, these changes are very small, particularly over the temperature range likely to be encountered in clinical use, so that cuff softening is unlikely to be a mechanism by which the seal pressure or ‘fit’ of an i-gel improves with time after insertion.

Acknowledgements

No external funding or competing interests declared.

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