

**Relative transmissivity of ultrasound coupling agents
commonly used by therapists in the UK**

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Abstract

Coupling agents are required when using therapeutic ultrasound to maximise acoustic contact between the transducer and the insonated tissue. Ultrasound beam power is attenuated to varying extents by different couplants and this may influence treatment efficacy, since therapeutic effects are dose-dependent. It is therefore important to know how well different couplants transmit ultrasound. In this study the transmission characteristics of a range of gel couplants were measured using a Radiation Force Balance. Data were collected for gels commonly used by UK therapists, and at the powers and frequencies advocated for low-intensity therapeutic practice. Transmissivities of standard couplants relative to degassed water varied between 95% and 108% (nominal 95% confidence intervals between 0% and 11%). The spread and ranking of transmissivities changed when the US frequency was varied. For clinical purposes, however, there was no significant difference between transmissivities of the gels under test.

Keywords

Therapeutic ultrasound, low intensity, couplant, gel, transmissivity, attenuation.

Introduction and Literature

Therapeutic ultrasound (US) has been shown to be efficacious in a wide variety of clinical applications including encouraging resolution of the inflammatory process and wound healing (Watson 2000) as well as transcutaneous drug delivery (Bly 1995). Physiological effects – which can be beneficial or deleterious - are governed by a range of parameters, including US frequency and intensity (Baker et al. 2001; Kollmann et al. 2005). Factors influencing the intensity of US reaching the tissue include output characteristics of the US generator, method of application and the type of medium employed to ensure good acoustic coupling between the US transducer and the insonated tissue. Considerable departures from intended intensity values can occur as a result of poorly calibrated equipment (Artho et al. 2002; Pye 1996), variations in treatment technique (Docker et al. 1982; Draper et al. 1993; Forrest and Rosen 1992; Griffin 1980; Merrick et al. 2002) and choice of acoustic couplant (Batjes and Klomp 1979; Casarotto et al. 2004; Docker et al. 1982; Klucinec et al. 2000; Merrick et al. 2002; Warren et al. 1976).

Previous studies have indicated that the transmissivities of couplants commonly employed at the time varied significantly, with some reducing the intensity of the US beam by as much as 80% (Cho 1984; Griffin 1980; Reid and Cummings 1973; Reid and Cummings 1977). Clearly if the clinician does not take account of this, inappropriate treatments may be administered. Such studies have suggested that aqueous gels may have less impact on beam intensity than some creams and oils that have been employed as couplants. However new couplant products are regularly made available, and usage varies from one country to another. Published studies have not compared many of the products commonly and currently used by therapists in the UK, and their methods and parameters are often limiting. For example collecting data at only one beam frequency (e.g. Cho 1984) or at a single beam intensity (e.g. Docker 1982); using thicknesses of gel which are clinically unrealistic (Griffin 1980); employing apparatus which encourages standing wave formation in the couplant with consequent impacts on transmitted beam energy (Balmaseda et al. 1986; Cho 1984; Reid and Cummings 1973; Reid and Cummings 1977). In some cases incomplete reporting of parameters (e.g. Docker et al. 1982; Reid and Cummings 1973) makes it difficult to gauge reliability of findings. Such factors may account for apparent discrepancies between findings of different studies concerning couplant transmission characteristics. For instance transmission by Aquasonic gel relative to distilled or degassed water measured in a range of studies (Batjes and Klomp 1979; Benson and McElnay 1988; Docker et al. 1982; Reid and Cummings 1973) varied between 80% and 123%. The aims of this study were to address some of these design issues, to collect data on couplant transmissivity and to gauge relevance to contemporary clinical practice.

Theoretical Considerations

Several processes of energy loss can occur when sound waves propagate through a medium or cross boundaries between media. Within a medium, beam intensity may be reduced by dispersion of different frequency components, wave-front divergence, absorption and conversion to heat, and by scattering off inhomogeneities within the medium (Hykes et al. 1992, chap 1). A mono-frequency beam is not subject to dispersion, and a collimated beam is parallel in the near-field (Zagzebski 1996) so wavefront divergence is not an issue. The primary processes of attenuation are therefore absorption and scattering, which are dependent upon the nature of the medium and its thickness (Chivers 1991).

At boundaries, reflection or refraction may occur. These processes are functions of the relative densities and speeds of sound in the two media – expressed mathematically as their acoustic impedances (Chivers 1991). Where impedances do not match, boundary reflection and refraction can attenuate the incident beam. Ultrasound couplants should provide optimum impedance matching for energy passing between the US head and insonated tissue, thereby maximising transmission. If no couplant were used, intervening air (with an acoustic impedance very different to that of the US head) would result in virtually zero transmission.

Nevertheless couplants themselves cause beam energy loss since they cannot be impedance-matched to both US head and tissue. Depending on couplant composition, absorption and scattering may also occur. A good couplant will have properties which minimise all these processes. It will be designed to

have an acoustic impedance close to that of both US head and skin, to be able to soak the skin to ensure good acoustic contact, to cause minimum absorption and to be homogeneous. Using thin layers of gel results in less absorption, and using couplants without air bubbles reduces scattering.

Experimental Design Considerations

Studies comparing the transmissivities of couplants may involve measurement of the transmitted beam power or of its physiological effects. One measure uses a piezo-electric transducer to convert pressure variations in the incident US beam into an electrical signal (e.g. Reid and Cummings 1973). Another uses a sensitive balance to measure the radiation force of the ultrasonic beam (e.g. Benson and McElnay 1994). Physiological-effect methods include use of miniature thermistors or thermocouples to measure the heating effect of the beam in tissue (e.g. Draper et al 1993). Studies employing these different methods have led to different conclusions about transmissivities (e.g. Draper et al. 1993; Warren et al. 1976). In this study a radiation force balance (RFB) was used because it enables measurement of beam power, rather than its physiological consequences, which may depend on other factors. The RFB also appears preferable to the piezo-electric method, in which the surface of the receiver forms a further boundary which the beam must cross before reaching the transducer. Reflection at this interface (which depends on the acoustic impedance of the medium) means that the measured power may be less than that at the interface. The RFB, on the other hand, gives a value for power at the couplant/target boundary, since a proportional relationship exists between beam power and force exerted on the reflecting target (Davidson 1991).

Previous studies have suggested that transmitted power is affected by couplant temperature (Lehmann et al. 1966; Oshikoya et al. 2000) and pressure exerted by the clinician via the transducer head (Klucinec 1997; Warren 1976). Such findings imply that these variables should be controlled during an investigation of couplant transmissivity.

Materials and methods

Direct power measurement by an RFB (EMS Precision Ultrasound Balance Model 110. Electromedical Supplies (Greenham) Ltd, Wantage, UK) was chosen for this study. It comprises a conical metal air-filled target immersed in a 1 litre container, and mounted independently on a frame supported by a sensitive electronic digital weighing balance. The container is filled with degassed water and has an acoustically absorbent butyl rubber liner. The apex of the target lies 20 mm below the surface of the US transducer head, which is held in place by a plastic collar resting on the container lining (see Figure 1). The balance reads the apparent weight of the target, buoyed up by the water. Incident US energy exerts a force on the target, whose vertical component registers as an increase in the apparent weight of the target. The balance was pre-calibrated by the suppliers and programmed with a scale factor which converts the weight reading to its equivalent temporally averaged and spatially integrated beam power. The accuracy of readings is given by the supplier as $\pm 10\%$ and the resolution of the apparatus as 0.05 W. The apparatus was newly acquired, and certified calibrated by the supplier to traceable national standards. The US beam was generated by an EMS Therasonic 455 therapeutic ultrasound unit (Electromedical Supplies (Greenham) Ltd, Wantage, UK) with a transducer head of ERA 4 cm², and BNR 5.0 max, emitting at 1.1 MHz or 3.4 MHz (data provided by manufacturer).

A 1 cm³ sample of the couplant was placed on the US head surface using a graduated syringe. This was held in place using a piece of PVC film (Sainsbury's General Purpose Clingfilm, J Sainsbury plc, London), of thickness < 30 μm . This arrangement created a flattened dome-shaped profile of maximum thickness 1.5 mm (see Figure 1). The film adhered to the sides of the US head, and was further secured with a rubber band. More viscous couplants are prone to contain bubbles, potentially causing significant beam scattering. Careful handling of the gels and rejection of samples with more than 2 or 3 visible bubbles aimed to minimise this problem, although invisible microbubbles may have been present and indeed could have been created during insonation.

Several aspects of design and usage aimed to mitigate problems experienced in previous research in this area. The use of a conical target and rubber liner ensures that very little energy is reflected back to the US transducer. Because of the curved profile of the PVC film, the majority of any reflection from it is not parallel to the incident beam. These features imply that standing waves formation

should be minimal. The water used was distilled and degassed by boiling for 15 minutes in order to minimise bubble formation and consequent scattering of the US beam. The apparatus, including the transducer head, target and liner, were visually checked for bubble formation before and after each period of data collection, and surfaces were wiped with cotton buds to remove any such accumulation

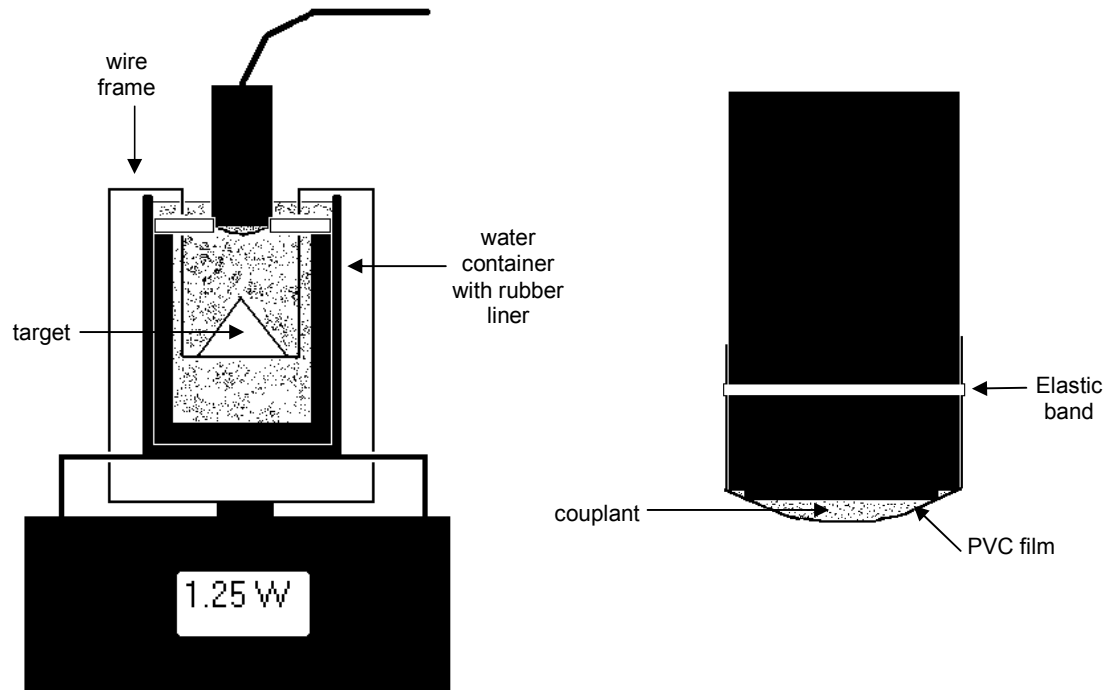


Fig. 1. Radiation force balance configuration and detail of US transducer head with sample held in place by PVC film and rubber band.

Initial data were gathered on a range of potentially confounding factors in order to establish their influence on the findings of the main study. US beam power could be affected by:

(a) the intervening PVC film. This may also attenuate or reflect the US beam. Therefore data were collected with water alone, and then with the film adhering to the underside of the plastic collar, with a layer of water held between it and the sound-head. This enabled measurement of the effect of the film on beam power.

(b) thickness of the gel layer. This might have a significant impact on beam intensity, so it was judged appropriate to investigate the effect of couplant layer thickness at various values. No published studies measuring the thickness of couplant layers in practice were found. Balmaseda *et al* (1986) claim that gel thickness may be less than 0.2 mm in practice, whilst Reid and Cumming (1977) suggest it could lie in the range 1-30 mm. In the main study the maximum thickness of the dome-shaped sample was 1.5 mm, which was judged to be at the upper end of typical gel thicknesses used in clinical practice. Greater and smaller values were also tested to see whether layer thickness impacted on transmitted intensity.

(c) temperature of the degassed water. The acoustic impedance of water varies with temperature (Kaye and Laby 2006), and a temperature rise is likely as energy absorbed by the rubber liner heats up the liner and thus the water. The potential impact of this rise therefore required investigation.

The data from all these initial investigations were gathered over a range of US powers but at only one frequency (3.4 MHz) and using only one type of couplant (SKF). In each investigation at least 30

transmitted power readings were taken at each nominal power value, as displayed on the US generator unit.

For the main study, data were collected for emitted powers of 0.4, 1.2, 2.0, 3.2, 4.0 and 6.0 W (with equivalent intensities between 0.1 and 1.5 W/cm²) all continuous, and at frequencies of 1.1 MHz and 3.4 MHz. The emitted powers are nominal values displayed by the generator. These parameters reflect those most commonly used by UK physiotherapists for therapeutic ultrasound (Watson 2000). For each sample, at least 30 readings of power measured by the RFB were taken at each frequency and nominal power over a period of weeks. The US generator was cycled through a computer-generated randomly-ordered sequence made up of 35 US applications, 7 at each nominal power value. The stable balance reading at each power was directly exported to a computer spreadsheet for subsequent analysis. The starting temperatures of the water and couplant were set in the range 21 ± 1 °C, and each cycle took less than 10 minutes, ensuring that the water temperature did not vary by more than 1 °C during data collection. The balance was zeroed whenever a zero-error occurred (the apparatus is subject to a zero drift of <0.1 W/hour according to the suppliers). The US generator was calibrated each week using the RFB with degassed water alone, and the weighing balance itself was calibrated using a mass of known weight at similar intervals. The whole apparatus set-up was placed away from sources of strong electromagnetic fields and draughts which might affect the balance.

The couplants under test were those in common use by physiotherapists in the UK, marketed as Aquasonic 100 (Parker Laboratories, New Jersey, USA), EMS Therasonic (Electromedical Supplies Ltd, Wantage, UK), JPM ultrasound gel (JPM Products, Ware, UK), KY gel (Johnson & Johnson, Maidenhead, UK), SKF Eko-gel (SKF Services, Billingshurst) and Physio-med ultrasonic transmission gel (Physiomed Services, Glossop, UK). For comparison purposes a topical analgesic gel, which may be applied using US, was also tested. This was Biofreeze (Performance Health, Export, USA).

For each gel type, average values were calculated for transmitted power at each nominal emitted power and at each frequency. The ratio of each transmitted power value to that of degassed water was then calculated for each couplant, providing a relative transmissivity value.

Results and Discussion

Effect of PVC film

Transmitted power was measured with a section of PVC film covering the lower surface of the plastic collar holding the US head in place. Water filled the 2 mm gap between the film and the US head. Over the range of US powers and at both frequencies, power transmitted through the film + water differed from that transmitted by degassed water alone by less than 1%. Therefore the presence of the film in subsequent readings with couplants was assumed to make only a minimal contribution to power reduction.

Effect of transducer couplant layer thickness

By using different volumes of gel, three different thicknesses of sample were obtained: 0.2 ± 0.1mm, 1.5 ± 0.5 mm and 6.0 ± 0.5 mm. Figure 2 charts the effect of couplant thickness on transmission at 3.4 MHz for SKF gel. Transmission decreases as thickness increases. For example at a nominal power output of 6.0 W, when maximum couplant layer thickness increased from 0.2 mm to 6.0 mm, mean transmitted power reduced from 6.20 W to 5.85 W. Confidence intervals are too small to be visible on the chart scale (±0.05 W max at 95% confidence) but suggest that the observed differences between these two layer thicknesses are statistically significant. However the differences between readings at 1.5 mm and 0.2 mm are not significant.

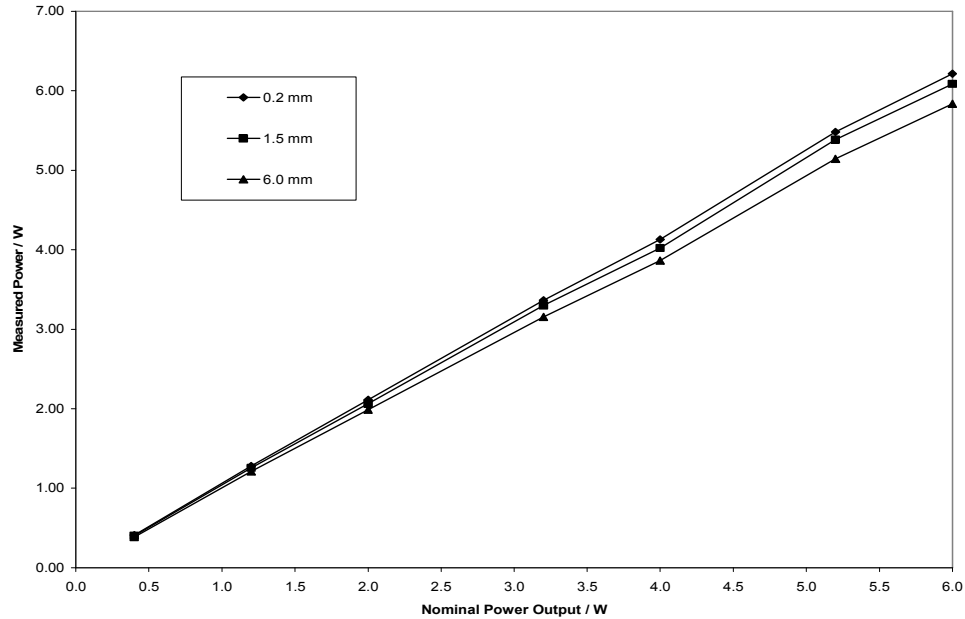


Fig. 2 Variation of transmitted power with thickness of SKF gel layer at 3.4 MHz. 95% confidence intervals are too small to show with clarity at this scale.

In clinical practice couplant layer thickness may sometimes be much less than 0.2 mm, perhaps of the order of micrometers. Transmission characteristics could be different at such values (Casarotto *et al* 2004). For the purposes of this study, the relative transmissivities of the samples would arguably be unaffected if thickness were held constant across samples.

Effect of water temperature

Transmitted power was measured across the range of nominal emitted powers at three different starting temperatures of water in the RFB, with no other couplant present. Figure 3 shows the results. The maximum 95% confidence interval is ± 0.04 W, indicating that the measured differences are statistically significant. Transmission is seen to decrease as temperature rises, with a mean value of $0.06 \text{ W}^\circ\text{C}$ at 5.2 W between 18.9°C and 25.8°C . This represents a 1% change in reading per $^\circ\text{C}$.

Measurements may be affected by the fact that the buoyancy of the target varies with water density, which is temperature dependent. This will affect the power reading given by the RFB: the suppliers suggest that readings may vary by 0.2% for each 1°C change in temperature. Since water temperature changes during data collection were no greater than 1°C , it is concluded that this variation did not materially alter the outcome of this study.

The data for all of these variables were only collected for one couplant (SKF) and at one frequency (3.4MHz). It is possible that different findings might be obtained at 1.1 MHz and for other couplants.

Effect of couplant type

Collected data for transmitted power values were found not to be distributed normally, so non-parametric statistical analysis (using SPSS 14 software) was applied to calculate ratios of median values with nominal confidence intervals of 95%.

Figures 4 and 5 plot the calculated relative transmissivities of couplants over a range of nominal emitted powers at each frequency. Identical scales are used to enable visual comparison between the graphs. Confidence intervals were different for each data point, and varied significantly at 0.1 and 0.3 W/cm^2 where the limits of RFB sensitivity were approached. At higher power values, CIs were in the range 4 – 8 % at 1.1 MHz and 2 - 5% at 3.4 MHz. At 3.4 MHz most of the confidence intervals overlap,

indicating very little detectable difference in transmissivities between the standard couplants at the 95% confidence level. At 1.1 MHz there are significant differences between some couplants at the same confidence level. The charts show the wider spread of transmissivities which is seen at 1.1 MHz. At this frequency several couplants have greater transmissivity than that of degassed water. Biofreeze, which is not a standard couplant, has a transmissivity significantly different from all the other couplants tested, being lower than 90% at both frequencies.

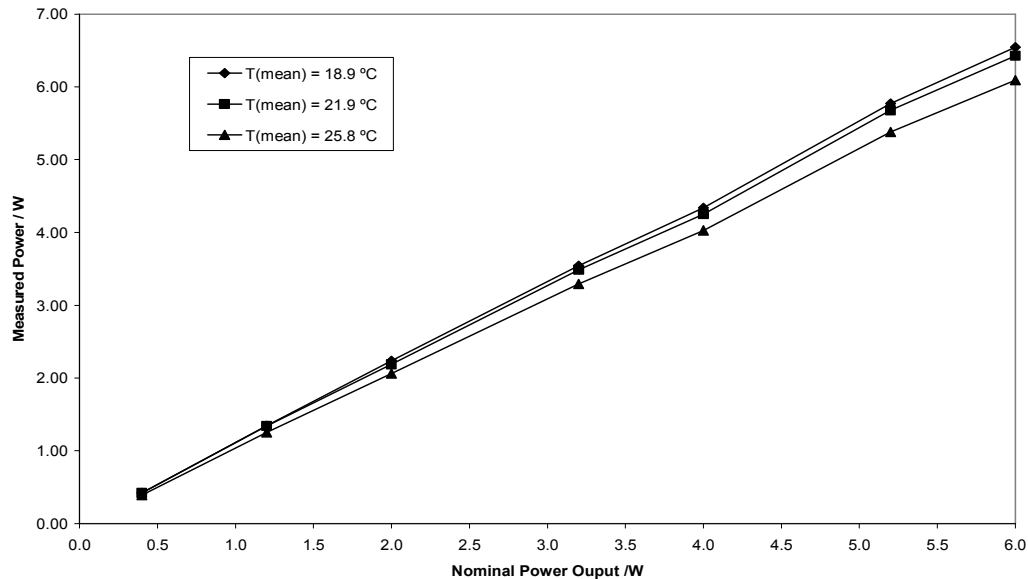


Fig 3. Effects of temperature variation on transmitted power through degassed water at various output powers. 95% Confidence intervals are too small to be visible at this scale..

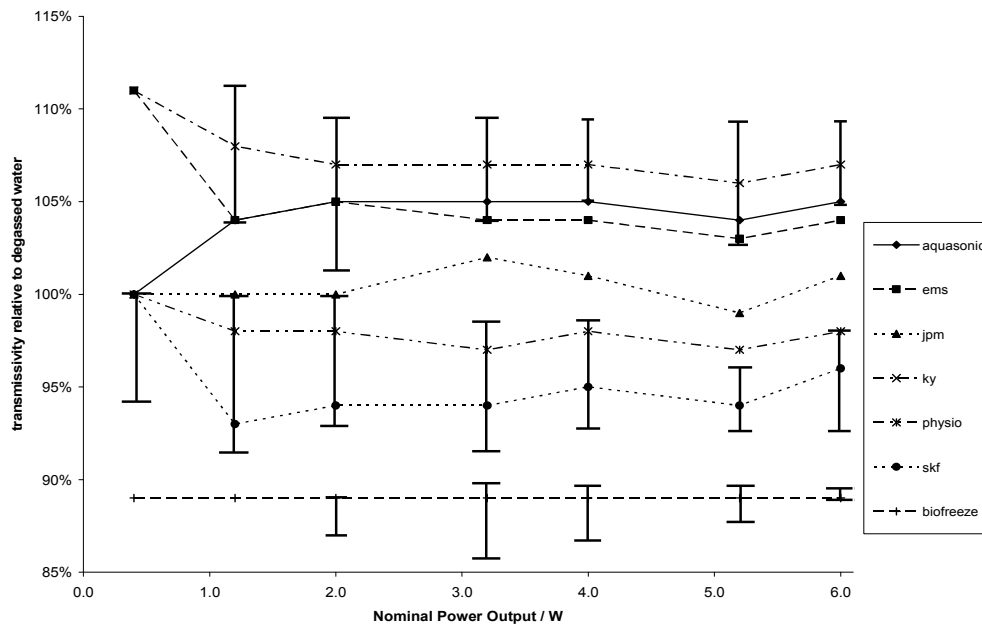


Fig. 4. Couplant transmissivity as a percentage of degassed water at 1.1 MHz. Some error bars are omitted for clarity. Those shown represent 95% confidence intervals for KY (best transmitter), SKF (worst transmitter of standard couplants) and Biofreeze (worst transmitter).

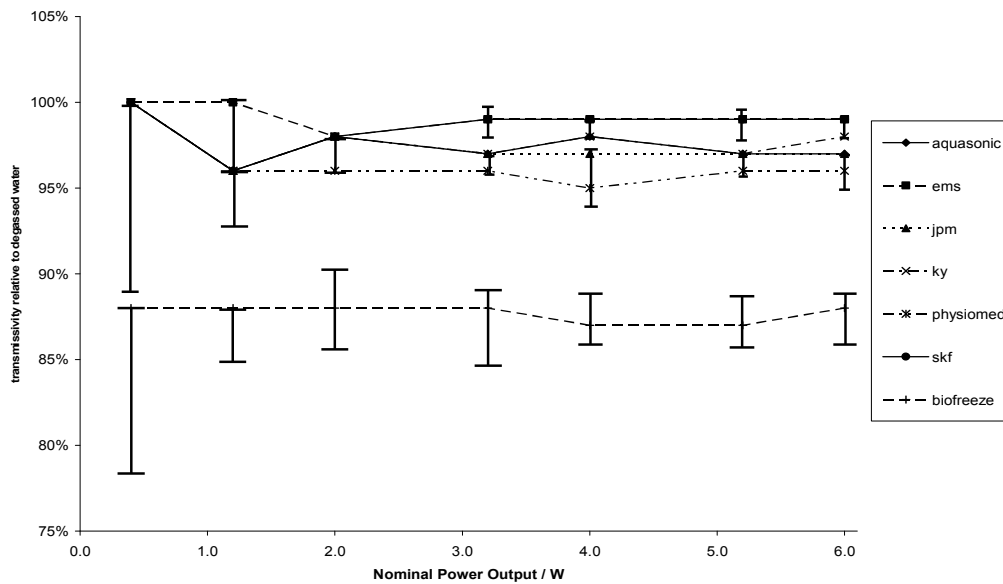


Fig. 5. Couplant transmissivity as a percentage of degassed water at 3.4 MHz. Some error bars are omitted for clarity. Those shown represent 95% confidence intervals for EMS (best transmitter), Physiomed (worst transmitter of standard couplants) and Biofreeze (worst transmitter).

Table 1 ranks couplant transmissivity relative to degassed water averaged over the range of beam powers used. It shows that the ranking is not the same at both frequencies.

Table 1. Ranked couplant transmissivities relative to degassed water at 1.1 MHz and 3.4 MHz

couplant	Mean relative transmissivity at 1.1 MHz	couplant	Mean relative transmissivity at 3.4 MHz
KY	108%	EMS	99%
EMS	105%	SKF	99%
Aquasonic	104%	KY	98%
JPM	100%	Aquasonic	97%
Physiomed	98%	JPM	97%
SKF	95%	Physiomed	96%
Biofreeze	89%	Biofreeze	88%

The markedly lower transmissivity values obtained for Biofreeze may have been due to the presence of substantial air-pockets in the gel, which were a function of its consistency and impossible to eliminate. Such bubbles are likely to be present in clinical practice, and so the findings here might still be considered meaningful.

Table 1 shows that, at 1.1 MHz, variations in relative transmissivity are larger than at 3.4 MHz. The ranking of transmissivities is also different at each frequency. Whereas degassed water is the best transmitter at 3.4 MHz, several gels perform better than water at 1.1 MHz.

Even thin layers of gel may result in some reduction in beam power, and thicker layers produce larger reductions. These facts suggest that both absorption and reflection processes are at work in the couplants. In the clinical situation there is no gel-film boundary at which reflection may take place, but there is a gel-skin boundary. The minimal reduction in power produced by the film in this study

suggests that its acoustic impedance is similar to that of water, and therefore of skin. Measured values, presented in Table 2, confirm this. We therefore contend that the acoustic behaviour of the apparatus used in this study is comparable to what would occur in clinical practice.

Table 2. Acoustic impedances of media used in this study

Medium	Acoustic impedance / $10^6 \text{ kg m}^{-2} \text{ s}^{-1}$	Source
Water (20°C)	1.48	Chivers 1991
Human skin	1.5 – 1.7	Payne 1991
PVC film	1.8	Tohmyoh and Saka 2003

The observed differences in US transmission due to gel-type and thickness are real but relatively small. At both frequencies these differences will result in intensity variations that are well within internationally agreed performance standards for therapeutic US generators (Hekkenberg 1998). Discrepancies between nominal and actual power outputs of generators used in clinical practice may often be a more significant contributor to intensity uncertainty than choice of couplant. Thus for practical purposes the clinician may use any of the couplants tested in the study, assured that the choice will not materially influence received intensity. Variations might be more significant, however, at the higher energies and different frequencies used in other clinical US applications.

Pose et al. (1979) suggest that price and other factors could be used in choosing appropriate couplants. There are certainly significant differences in cost between the gels under test. A search in February 2006 revealed prices for 1 litre of the couplants under test (excluding Biofreeze) varying between £4.50 and £42. Viscosity varies between gels and might also usefully be considered, since more viscous gels are easier to confine to one surface location, but are more prone to contain air bubbles on application.

Of the couplants considered here, only Aquasonic, EMS and KY gel have been subject to scrutiny by other published studies. Their findings are summarised in Table 3 but several are not strictly comparable for reasons given in the commentary. Data are for gel thicknesses around 1 - 3 mm and powers in the range 0.3 - 3.5 W unless otherwise stated.

Balmaseda et al. (1986) compared Aquasonic to tap water. Their apparatus produced substantial standing wave formation between US emitter and receiver at thicknesses less than 2 mm, and (possibly in consequence) their findings for Aquasonic differ substantially from those of other studies. Cho (1984) ascribes the relatively low value obtained for KY gel to the generation of bubbles during insonation and concluded that this gel should not be used as a couplant. However standing wave formation was an unacknowledged feature of the study's design. Docker et al. (1982) express relative transmissivities in decibels and the data in the table are recalculations using their data. Their experimental description is inadequate and does not give figures for US power or gel thickness. The configuration of apparatus in the studies Reid and Cummings (1973 and 1977) was subject to standing wave formation, but they argue that their results would not differ significantly in the absence of standing waves. Warren et al. (1976) used a set-up which avoided standing wave formation.

The data of several of these studies are not strictly comparable to our own since they were gathered at different frequencies. However the weight of evidence appears to lead to the same conclusion as ours, that differences in transmissivity between the gels under test are not clinically significant.

Table 3. Findings of previous research on some gels considered in this study

Transmissivity relative to water			
Couplant	Aquasonic	EMS	KY
Balmaseda <i>et al</i> (1986)	<50% at 1 MHz	-	-
Batjes and Klomp (1979)	107% at 1 MHz	-	-
Cho (1984)	-	-	74% ($\pm 5\%$ SD) at 1 MHz
Docker <i>et al</i> (1982)	112% at 2 MHz	107% at 2 MHz	109% at 2 MHz
Reid and Cummings (1973)	126% at 870 KHz	-	-
Reid and Cummings (1977)	123% (95%CI:13%) at 870 kHz	-	-
Warren <i>et al</i> (1976)	~90% at 1 MHz	-	-
Benson and McElnay (1988)	80% at 1.5 MHz 98% at 3.0 MHz	-	-

The present study has a number of limitations. The behaviour of the US generator used might have affected some of our findings. During data collection, a range of measured values was obtained at each nominal power output. This range was not normally distributed and was wider at 1.1 MHz than at 3.4 MHz. It may be that the generator output was less stable at the lower frequency. An appropriate non-parametric measure of the generator stability is the ratio of the inter-quartile range to the median power value for distilled water over the course of the study. Typically this ratio was less than 1% at 3.4 MHz but up to 10% at 1.1 MHz. It was highest at the lowest power values where the sensitivity of the balance became more significant. Such variations in generator output will have introduced uncertainty to the values calculated for relative transmissivity, particularly at 1.1 MHz. This is reflected in the confidence intervals, but these indicate that the limitations identified do not undermine the conclusions drawn.

The radiation force balance was initially calibrated to national standards by the supplier, but was not recalibrated to a known US source during the rest of the study. The fact that average readings for each couplant stayed constant for the duration of the study might suggest that the RFB calibration did not vary significantly over the period.

The study considered transmissivity of the couplants that are, in the experience of the authors, mostly widely used by therapists in the UK. Research data on actual use of couplants is not available, and it may be that some other media which were not tested are in common use. The frequencies and power values used reflect those recommended for clinical applications such as resolution of inflammation and promotion of healing (Robertson and Baker 2001; Watson 2000). It is recognised that ultrasound is used at other frequencies and powers for applications such as diagnostic imaging and tumour ablation. Quite different findings might be obtained for couplants used in such applications.

Future research might consider the transmission characteristics of couplants at frequencies and powers used in other clinical applications of US. There are also other media which may be used with therapeutic ultrasound – one group of interest being wound dressings. Therapeutic US has been shown to be of benefit in chronic wound management (Uhlemann *et al.* 2003), but there is

uncertainty as to whether US can penetrate the many types of dressing used on many wounds. A study of transmissivities of dressings commonly used in the UK is planned by the authors.

Summary and conclusions

This study has shown that, at frequencies and powers typically used for therapeutic ultrasound, there is no clinically significant difference in transmissivities of gel couplants in common clinical use in the UK. It suggests that the choice of couplant may be made on criteria other than transmissivity. There are measurable differences in transmission characteristics at different frequencies, however, and it may be that these could reach clinical significance at other frequencies and powers.

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