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**AN *IN VITRO* STUDY OF FLUORIDE
ION RELEASE FROM ORTHODONTIC
ELASTOMERIC MODULES**

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SUMMARY

Fixed orthodontic appliances encourage the accumulation of food debris and plaque, while at the same time obstructing thorough oral hygiene procedures. This combination increases the risk of the formation of areas of enamel demineralisation during orthodontic treatment.

The addition of fluoride to community water supplies, toothpastes and mouthrinses has provided ready sources of the fluoride ion for the prevention of enamel demineralisation and dental caries in the general population. Fluoride has also proven effective in the remineralisation of enamel exhibiting early signs of demineralisation.

Manufacturers have incorporated fluoride in orthodontic materials and products, with the anticipation that slow release of the fluoride ion intraorally will assist in the prevention or reversal of the early enamel demineralised area, known as the "white spot lesion". In line with these objectives, orthodontic elastomeric modules have been impregnated recently with fluoride salts, in particular, stannous fluoride.

An *in vitro* study was designed to test and evaluate in an aqueous environment, four proprietary brands of fluoride impregnated orthodontic elastomeric modules for:

- i. The amount of fluoride ion released.
- ii. The rate of fluoride ion release.
- iii. The differences in rate and level of fluoride ion released, over 31 days.

The modules contained either stannous fluoride or a combination of stannous fluoride and sodium fluoride at concentrations of 1.43 - 1.5% (weight/volume).

Modules were placed in 2 mls of double distilled deionised water in polystyrene bottles and left at 37° Celsius for seven designated time periods. At the conclusion of each time period the modules were transferred to new bottles and water. The water samples collected were stored for examination at a later time.

At the end of the final time period (31 days) all water samples were tested for fluoride ion levels with a fluoride specific electrode and a digital pH meter. Each water sample was mixed with an equal volume of adjustment buffer and the reading obtained in millivolts was converted on the calibration curve that had been previously established.

An analysis of variance and the Student-Newman-Keul test (used for multiple comparisons between groups) established the statistical significance of the experimental findings of each group relative to the others.

The results indicated that the fluoride impregnated commercially available products tested, did release fluoride over a thirty-one day period, in significant amounts. The four products showed variation in the absolute amount and individual rates of fluoride release. Similarities were observed, however, in the profile of the percentage release of fluoride ion over 31 days. All products had released at least 50% of the total fluoride ion release during the experiment, at the tenth day.

The major findings from this study were that:

- i. Fluoride was released from the elastomeric modules marketed as fluoride impregnated over a 744 hour (31 day) experimental period.
- ii. The initial rate (0 - 72 hours) of fluoride release observed was greater than that between 72 and 744 hours for each sample tested.

- iii. Despite the similarities in the amount of fluoride incorporated into each product, the differences in individual rate and absolute level of fluoride ion release amongst the four module types tested were significant, over the 744 hour (31 day) experimental period.

The findings from this study suggest that the fluoride release experienced over the first ten days could be beneficial if fluoride was incorporated into elastomeric separating rings, which are used prior to orthodontic banding.

Further studies are required however, to evaluate both *in vivo* and *in vitro*, the effect on dental enamel of fluoride ion release from the orthodontic elastomeric modules.

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DEDICATION

To my teachers
who have fostered my self-awareness.

II Corinthians 12:7-10

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1. INTRODUCTION

The white spot enamel lesion is the earliest clinical manifestation of enamel demineralisation in the human dentition. Øgaard (1989) described these lesions as "optical phenomena" resulting from mineral loss from the surface and sub-surface layers of the tooth enamel.

Several independent studies of patients wearing fixed orthodontic appliances have shown a relationship between these appliances and an increased susceptibility to enamel demineralisation (Gorelick et al 1982; Mitchell 1992a; Mizrahi 1982; Zachrisson and Zachrisson 1971a and Artun and Thylstrup 1989). This increased incidence of white spot formation in patients undergoing fixed orthodontic appliance therapy, was associated by Artun and Brobakken (1986) and Wisth and Nord (1977), with the difficulty in maintaining adequate oral hygiene and the predilection for plaque retention around the appliance.

The physical nature of orthodontic appliances was cited by Mitchell (1992a) as a contributory factor to the process of enamel demineralisation in the orthodontic patient. Other authors have suggested that a change in profile of the microbiology of the plaque in patients wearing fixed orthodontic appliances, could be a factor in the increased prevalence of white spot formation during orthodontic treatment (Balenseifen and Madonia 1970; Bloom and Brown 1964; Corbett et al 1981; Rosenbloom and Tinanoff, 1991).

Dean (1938) was the first to report the anti-caries effects of fluoride and since that time, fluoride has been shown to be a caries preventive agent by many authors (Craig 1987; Boyd 1993; Driscoll et al 1981; Featherstone et al 1982; Geiger et al 1992; Jeansonne and Feagin 1979; Muhler 1960; Øgaard 1990; Shellis and Duckworth 1994). The recognised ability of fluoride to prevent enamel demineralisation and influence enamel remineralisation, has resulted in its incorporation into materials used in orthodontic therapy (Levine 1991).

This has been considered a useful mechanism and a potential avenue for the prevention and reversal of the enamel white spot lesion formation during orthodontic therapy.

Materials used as vehicles for the delivery of the fluoride ion to susceptible sites include; gels, mouthrinses, topical fluorides and fluoride containing dentifrices (Shannon 1977; Hirschfield 1978; Zachrisson 1975; Saloum and Sondhi 1987 and Øgaard et al 1980). More recently, fluoride releasing orthodontic cements, varnishes and bonding resins have been manufactured in an effort to increase the availability of the fluoride ion throughout orthodontic treatment (Wilson et al 1985; Sadowsky et al 1983; Adriaens et al 1990; Bishara et al 1991 and Underwood et al 1989).

The orthodontic elastomeric module is the most recent of the orthodontic materials to be used as a vehicle for the slow release of the fluoride ion during orthodontic treatment (Mitchell 1992a and Baty et al 1994). As with the cements, varnishes and bonding resins, the modules have been fluoride impregnated and designed to release fluoride closest to the area of highest susceptibility, namely, the appliance/tooth interface.

The original work of this thesis was designed to test the hypothesis that the fluoride ion is released from four proprietary brands of orthodontic elastomeric module, when these products are placed in an aqueous environment.

This *in vitro* study aimed to evaluate the fluoride ion release profile from fluoride impregnated orthodontic elastomeric modules. An experiment was designed to determine the ability of commercially available fluoride impregnated orthodontic elastomeric modules to release fluoride ions. The objectives of this study were to determine:

- i. The amount of fluoride ion released.
- ii. The rate of fluoride ion release.
- iii. The differences in rate and level of fluoride ion release from four proprietary brands of fluoride impregnated orthodontic elastomeric modules, in an aqueous environment.

2. REVIEW OF LITERATURE

2.1 Orthodontic Treatment and Enamel Demineralisation

Dental caries is a multifactorial disease, which manifests as an imbalance between the demineralisation and remineralisation of tooth enamel (Øgaard et al 1988a).

The factors contributing to the caries process include:

- i. The presence of cariogenic micro-organisms.
- ii. The availability of a suitable substrate for the micro-organisms to produce low pH by-products (organic acids).
- iii. The presence of susceptible sites for enamel demineralisation.
- iv. An interaction of the above factors over a period of time.

Mitchell (1992a) and Zachrisson and Zachrisson (1971b) noted that the presence of fixed orthodontic appliances hindered tooth cleaning and, consequently favoured the retention of food debris and plaque. With suitable substrate present, the orthodontic patient is, according to numerous authors, more susceptible to enamel demineralisation (Wisth and Nord 1977; Øgaard et al 1988b; Øgaard 1989; Mizrahi 1982; Mizrahi 1983; Gorelick et al 1982; Artun and Brobakken 1986 and Mitchell 1992a).

2.1.1 Enamel demineralisation

Tooth enamel responds to the prolonged exposure to organic acid, with the formation of a clinically demarcated opaque white lesion. This area, according to Øgaard et al (1988a), is softer than the surrounding sound enamel and is characterised by a subsurface lesion covered by a relatively intact surface layer. It is the earliest clinical manifestation of the caries process (Gorelick et al 1982).

The surface softening of the white spot lesion is due to the selective removal of interprismatic substance of the enamel, while the deeper, subsurface lesion is the result of a more pronounced dissolution of the enamel (Øgaard 1988a). Johnson (1967) and others, have described minute pathways through the relatively intact surface layer which they suggest act as a communication to the sub-surface carious enamel lesion.

The existence of the relatively intact surface layer of the white spot lesion was investigated, in a scanning electron microscope study by Øgaard (1988a) and Haikel et al (1983). They reported ultrastructural differences in the physical composition of the surface enamel compared to the deeper layers. The surface enamel has a greater resistance to carious dissolution, owing to its higher mineral and lower water content.

The relatively intact enamel surface layer is formed under the influence of fluoride from the oral environment (Borsboom et al 1985) and also the deposition of mineral ions from the dissolving subsurface lesion (Aobe et al 1981).

2.1.2 Incidence of enamel demineralisation in orthodontically treated patients

The physical extent of the early demineralised lesion was investigated by Øgaard et al (1988a) and O'Reilly and Featherstone (1987). Using premolars scheduled for extraction, Øgaard et al (1988a) found that, in the absence of any fluoride supplementation, clinically visible white spot lesions were seen within four weeks of the placement of orthodontic bands. In situations where plaque was allowed to accumulate, the use of microradiographic and scanning electron micrographic examinations also revealed marked and localised demineralisation of the surface of the enamel.

O'Reilly and Featherstone (1987) also studied premolars scheduled for extraction and investigated the extent of demineralisation following orthodontic band placement. In this study the control teeth were those teeth banded and not exposed to fluoride supplementation. Following a one month period they found enamel lesions demonstrating up to 15% demineralisation to a depth of 50 μ m of the enamel surface layer of the control group teeth. These enamel lesions were not clinically detectable.

Davies et al (1991) and Addy et al (1988) found that although irregularly placed teeth retain more plaque, there were no statistically significant differences in their incidence of caries and gingivitis, compared to uncrowded arches. The placement of fixed orthodontic appliances, however, changed this balance increasing the incidence of enamel demineralisation.

Examining the problem of caries initiation in orthodontic patients covers several aspects:

- i. The overall prevalence of new enamel demineralisation during orthodontic treatment.
- ii. The distribution of the enamel demineralisation occurring during orthodontic treatment.
- iii. The differences in the patterns of demineralisation following various appliance and adhesive material use during orthodontic treatment.

Mitchell (1992a) reviewed 11 studies of the topic and found that the reported prevalence of enamel demineralisation in orthodontically treated patients, ranged from 2 to 95%. He indicated that the wide range of results was due to variation in the methods of data collection and interpretation and study design. Most studies found an increased prevalence of enamel demineralisation in patients wearing fixed orthodontic appliances when compared with a control group who did not have orthodontic appliances placed (Stratemann and Shannon 1974; Gorelick et al 1982; Mizrahi 1982; Artun and Brobakken 1986; Geiger et al 1988 and Øgaard 1989).

Gorelick et al (1982) showed that the length of treatment time did not affect the incidence of white spots. The same incidence of 50% was recorded for teeth banded or bonded for 12 to 16 months as for those of 36 months. However, the incidence and severity of enamel white spots as measured by the Opacity Index, was found by Mizrahi (1982) in a cross-sectional study of 796 patients, to increase during orthodontic treatment.

Geiger et al (1988), Øgaard (1989) and Artun and Brobakken (1986) also found a greater incidence of demineralisation in orthodontically treated patients, in spite of a concomitant fluoride mouthrinsing program. However, Stratemann and Shannon (1974) in their observations of orthodontically treated patients with established demineralised areas, found that the rate of progression of these demineralised areas was decreased with the daily use of 0.4% stannous fluoride gel.

The distribution of the demineralised areas on the teeth of orthodontic patients wearing fixed orthodontic appliances was also studied by several investigators. Maxillary incisors, first permanent molars, maxillary canines and mandibular premolars were found to be the most frequently demineralised teeth (Gorelick et al 1982; Mizrahi 1983; Øgaard 1989 and Geiger et al 1988).

The pattern of white spot lesion distribution on the surfaces of the teeth of orthodontic patients was investigated by Zachrisson and Zachrisson (1971b) and Wisth and Nord (1977). They found that there was a change in the distribution of demineralised areas with an increased incidence of buccal and lingual smooth surface areas of demineralisation. In contrast, in the control non-orthodontically treated population, the pattern consisted mainly of occlusal and proximal, that is, mesial and distal, lesions. Mizrahi (1983), found that the cervical and middle thirds of the vestibular and lingual surfaces of the dentition were most commonly affected by enamel demineralisation. Artun and Brobakken (1986) confirmed that the gingival surface areas directly under areas of bracket placement, were more frequently demineralised in orthodontic patients.

The incidence, tooth location and specific site of demineralisation during orthodontic treatment is believed to be associated with the changes in amount and distribution of dental plaque. The changes in nature and species of the micro-organisms of plaque, are also believed to influence the incidence of enamel demineralisation (Balenseifen and Madonia 1970).

2.1.3 Alterations in oral microbiology during orthodontic therapy

With the reported increase in incidence of enamel demineralisation in orthodontic patients, research has focused on the changes in aetiological factors associated with the caries process, during orthodontic treatment.

The presence of cariogenic micro-organisms is central to the caries process. Bloom and Brown (1964) in their study of pre-treatment, mid-treatment and post-treatment saliva samples, found that following the placement of orthodontic fixed appliances the plaque and salivary levels of cariogenic micro-organisms increased. This finding was confirmed in the later studies of Sakmaki and Bahn (1967), Balenseifen and Madonia (1970), Corbett et al (1981), Scheie et al (1984), Huser et al (1990) and Rosenbloom and Tinanoff (1991).

The level of *Streptococcus mutans*, which has been strongly associated with caries development in the human, was found to be raised in orthodontic patients (Corbett et al 1981; Scheie et al 1984 and Rosenbloom and Tinanoff 1991). Also *Lactobacilli* counts were found to be elevated in orthodontic patients (Balenseifen and Madonia 1970; Bloom and Brown 1964 and Sakmaki and Bahn 1967).

The nature of the fit and adhesive used for the bonding and banding was also associated with the increased presence of micro-organisms. In their study of the microbial composition of dental plaque of ten patients undergoing orthodontic treatment, Huser and Lang (1990) used dark-field microscopy to show the increase in the levels of *spirochetes*, *motilrods*, *filaments* and *fusiforms*, in sites of orthodontic banding. These micro-organisms have been associated with increase in incidence of periodontal disease.

The tooth-bracket margin has attracted the attention of investigators examining the nature of the bond of composite resins to tooth and bracket. Gwinnett and Ceen (1979) found that in spite of excellent oral hygiene, there was an "abundance of mature plaque" at this margin.

Specifically, their scanning electron microscope examination of 100 debonded brackets, showed that the most frequent site of enamel demineralisation appeared at the junction between the bonding resin and the enamel, peripheral and gingival to the bracket base.

Most authors agreed that minimising the levels of dental plaque through meticulous oral hygiene during orthodontic treatment was a major influence on the reduced incidence of enamel demineralisation. In addition, preventive or prophylactic programs for patients undergoing orthodontic treatment have been suggested by Huser et al (1990) and Gwinnett and Ceen (1979) as being beneficial in the reduction of the incidence of enamel demineralisation.

2.1.4 Prevention of enamel demineralisation during orthodontic therapy

Central to the prevention of enamel demineralisation during orthodontic treatment, is the clinical management of the aetiological factors responsible for caries formation.

Saloum and Sondhi (1987) noted that oral hygiene is complicated by the presence of orthodontic appliances, and suggested that the orthodontist can assist in the prevention of enamel demineralisation, primarily through the education of patients. By setting aside the appropriate amount of time for thorough oral hygiene and dietary instruction for the orthodontic patient, the orthodontist can minimise the risks of gingival inflammation, enamel demineralisation and dental caries (Harvey and Powell 1981).

During orthodontic treatment Artun and Brobakken (1986) have suggested that professional oral hygiene instruction and maintenance are effective but labour intensive. Lundstrom et al (1980), however, supported periodic re-enforcement of oral hygiene techniques in an effort to keep levels of motivation high.

Plaque formation on teeth creates susceptible sites for enamel demineralisation. Plaque can be removed from teeth mechanically or controlled chemically. Mechanical plaque removal is usually achieved by the twice daily brushing of teeth using a standard soft small-head toothbrush and an interdental brush for proximal sites. Chemically, plaque can be controlled by the use of therapeutic mouthrinses and of those available, chlorhexidine, according to Hogg (1990), is the most effective.

The retention of plaque around the orthodontic appliances can also be reduced. Mitchell (1992a) suggested that the removal of composite flash around bracket bases and a regular check of the patency of cements used for band placement, are helpful strategies for the reduction of plaque accumulation.

Many attempts have been made to protect the enamel surface around the orthodontic attachments. Mitchell (1992a) described these methods as being in two groups:

- i. Methods to protect tooth around and beneath the orthodontic attachment.
- ii. Methods used to directly strengthen enamel and reduce its acid susceptibility.

Lee et al (1973) and Tillery et al (1976) advocated the use of a protective polymer adhesive on the surface of teeth to be banded. Tillery et al (1976) used *in vitro* studies on extracted premolar teeth to support their claim that polymer adhesives are a more reliable method of protection against demineralisation than pre-banding applications of acidulated phosphate fluoride and stannous fluoride.

Brandt (1980) suggested a simple prophylaxis, etching and sealing of the buccal surfaces of molar teeth prior to band cementation. He claimed this procedure reduced or eliminated demineralisation in the area treated.

Harvey and Powell (1981) described the importance of using topical fluoride applications prior to, during and following orthodontic treatment, to enhance the resistance of enamel to organic acids. Shannon (1981) independently supported these recommendations by advising regular topical fluoride applications and home mouthrinsing programs for orthodontic patients.

The anticaries mechanisms and efficacy of fluoride has been reported in the literature extensively. Shannon (1981) notes that along with its ability to reduce the solubility of tooth surfaces, stannous fluoride also decreases the accumulation of plaque, resulting in an antibacterial effect on enamel surfaces. Fluoride has proven as both preventive and regenerative with respect to enamel demineralisation (Silverstone 1983b) and as such, will be described in terms of its known mechanisms and commonly used applications for the orthodontic patient.

2.2 Fluoride Therapies and Enamel Remineralisation

Enamel is in dynamic equilibrium with its environment (Beltran and Burt 1988). Early changes favouring demineralisation and the formation of dental caries, were once thought to be progressive and inevitable.

It is now known that early carious lesion, (the white spot lesion), is capable of remineralisation (O'Mullane 1994). The fate of a white spot lesion has, therefore, one of three alternatives:

- i. It can progress to eventually exhibit clinical cavitation.
- ii. It can remain static.
- iii. It can reverse, through remineralisation.

Koulourides et al (1980) showed that the fluoride ion promotes the remineralisation process and that the arrested lesion is subsequently more resistant to caries attack than a similar unaffected enamel area.

Shellis and Duckworth (1994), in their review of the caries-preventive mechanisms of fluoride, suggested four methods of action through which fluoride may cause a reversal of the caries process. These are:

- i. The reduction of mineral solubility.
- ii. The inhibition of acid formation by plaque bacteria.
- iii. The inhibition of mineral dissolution.
- iv. The promotion of enamel remineralisation.

These mechanisms may act singularly or in combination, however the total effect of fluoride is to tip the physiological balance in favour of enamel remineralisation.

2.2.1 Fluoride pre-eruptive effects on enamel

In 1945 Gerould sought an explanation of the pre-eruptive effects of systemic fluoride administration on the developing enamel. Using electron microscopy, Gerould found fluorosed enamel surfaces were rougher than that of normal teeth. He suggested that fluoride incorporated into the tooth structure during the formative or calcification periods was laid down as acid resistant calcium fluorapatite, whereas post calcification, the fluoride deposits as a surface layer of calcium fluoride.

Beltran and Burt (1988) suggested that the main benefits of pre-eruptive ingestion of fluoride are the improved crystallinity of the enamel and the reduction in enamel solubility. They stated that the amount of fluoride deposited pre-eruptively depended on the concentration of the fluoride in food, water or any supplements ingested. The length of the ingestion period and the length of the pre-eruptive maturation phase of the enamel were also suggested as being significant.

Mellberg (1977) examined the enamel effects resulting from systemically acquired fluoride. He found that although enamel may be 1000 μm (1mm) thick, high concentrations of fluoride are normally only found in the outer 30 - 50 μm . This surface layer, rich with fluoride ions was established, according to Mellberg (1977), during a pre-eruptive maturation phase of mineral deposition and resulted in the formation of enamel with improved crystal structure that was less soluble in acid and consequently less susceptible to caries.

The crystal structure and morphology of teeth was also the subject of a study by Foreman and Retzlaff (1990). Following studies which showed equivocal relationships between systemic fluoride and occlusal anatomy of the first permanent molars, Foreman and Retzlaff found there was no direct relationship between groove depth and widths of mandibular permanent first molars and their exposure to fluoride during amelogenesis.

The present opinion, according to O'Mullane (1994) supports the fact that although the pre-eruptive effects of fluoride can be demonstrated, the main therapeutic advantages of fluoride operate in the post-eruptive environment.

2.2.2 Fluoride post-eruptive effects on enamel

The increasing awareness of the importance of the post-eruptive effects of fluoride on enamel (Nelson et al 1983) has resulted in the trend towards improving the efficacy of topical fluoride treatments (Shellis and Duckworth 1994).

This trend is the result of a revised understanding of the cariostatic mechanisms afforded by fluoride (Fejerskov et al 1981). Fluoride has been shown to:

- i. Widely affect the equilibrium of the calcium phosphate system associated with enamel.
- ii. Affect the acid production and metabolism of cariogenic bacterial species (Bounoure and Vezin 1980).
- iii. Provide a source for the establishment of reservoirs of fluoride in the tooth and wider oral environment.

Fluoride has, according to Shellis and Duckworth (1994), a strong affinity to apatite. The inorganic substance of tooth enamel is a form of hydroxyapatite [(HA)], $[\text{Ca}_5(\text{PO}_4)_3\text{OH}]$, and the fluoride ion is attracted to it because of its electronegative character and its convenient, small ionic size.

With the incorporation of the fluoride ion into the hydroxyapatite crystal, the fluorapatite crystal is more stable than hydroxyapatite due to the formation of stronger bonding between the adjacent calcium ions. This results in fluorapatite having a more compact structure and hence a lower solubility product.

The effect of this conversion of hydroxy to fluorapatite on the white spot lesion formation is according to Shellis and Duckworth (1994) manifested in the reduction of calcium and phosphate ions dissolved at any given pH in the fluorapatite, as compared with the hydroxyapatite crystals.

Fluoride has also been found, by Barbakow et al (1983), to reduce the dissolution rate of enamel. According to Shellis and Duckworth (1994) the rate of enamel dissolution is directly proportional to the rate of progression of carious lesions. The concentration of fluoride at the crystal surface and the fluoride concentration of the surrounding environment during demineralisation both effect the rate of dissolution. Also, the availability of both the bound and the free fluoride ions are important in their effects on oral bacteria.

Fluoride has several documented effects on plaque bacteria. The first of these is the reduction of the acid production of the bacteria, which, according to Shellis and Duckworth (1994), occurs even in low concentrations of fluoride. It acts by interfering with the control of intracellular pH. When external conditions are acidic, the bacteria maintain the neutral intracellular environment needed for function, by expelling hydrogen ions from the cell. Fluoride it appears, alters the membrane permeability to hydrogen ions, thus indirectly resulting in a decrease in bacterial acid production.

Secondly, fluoride has been identified as a possible agent in the alteration of the ecology of dental plaque (Tinanoff and Weeks 1979). This occurs through the removal of the pH and environmental advantages previously held by *Streptococcus mutans* and other acidogenic micro-organisms.

The sources of the fluoride available post-eruptively have been identified as important factors in long term protection against enamel demineralisation. If fluoride is to be considered an effective therapeutic agent, it should be available over an extended period of time in the oral cavity.

Saliva and its clearance is an important feature of fluoride rate retention intraorally. Following the use of fluoridated mouthwashes and toothpastes, Duckworth et al (1991), found that fluoride levels of saliva decrease slowly for up to two hours. The regular use of these products builds fluoride concentrations in both saliva and plaque to a base level over two weeks. Plaque is also thought to be an important fluoride reservoir because of its proximity to the teeth (Backer-Dirks 1966).

Within these two reservoirs (saliva and plaque) two forms of fluoride have been identified:

- i. Calcium fluoride.
- ii. Plaque bound fluoride.

These reservoirs of fluoride, as well as preventing demineralisation, act as sources of fluoride ion for the remineralisation and potential reversal of the white spot lesion.

2.2.3 Fluoride and enamel remineralisation

Beltran and Burt (1988) stated that the ability for enamel to undergo remineralisation could be regarded as a natural defence mechanism. For enamel remineralisation to occur the tooth surface should be intact, with only the evidence of initial demineralisation being present (van Dorp et al 1988 and Artun and Thylstrup 1989). Furthermore, there needs to be a reservoir or source of ions to promote the remineralisation (Featherstone et al 1981) and these events can only take place in the context of a favourable pH (Featherstone et al 1982).

Fluoride, according to Borsboom et al (1985) and O'Mullane (1994) promotes the remineralisation process and the concentration required for this process to occur is considered to be much lower than the concentrations found in commercially available topical fluoride agents (O'Mullane 1994).

The type of fluoride used in remineralisation has also been a focus for investigation. Øgaard et al (1988a) found that topically applied neutral fluoride agents, such as sodium fluoride, inhibited but did not completely stop carious lesion development. In their study a topical application of 0.6% sodium fluoride at pH 1.9 retarded enamel demineralisation better than daily rinsing with neutral sodium fluoride. This finding has been supported by Joost Larsen et al (1981) and Tinanoff et al (1976). However, comparisons between sodium fluoride and sodium monofluophosphate suggest, according to Shellis and Duckworth (1994), that the sodium fluoride is superior for the establishment of intra-oral fluoride reservoirs. This may be realised in the precipitation of calcium fluoride on the tooth surface (Saxegaard and Rølla 1989) which, being sparingly soluble, acts as a slow-release source of fluoride ions.

Based on a clinical trial, O'Reilly and Featherstone (1987), suggested that complete protection for the orthodontic patient in inhibiting demineralisation and promoting remineralisation of surfaces at risk, can be obtained through the daily home use of:

- i. A fluoride containing toothpaste.

- ii. A low-concentration (0.05% sodium fluoride) commercially available fluoride mouthrinse.

2.2.4 Therapeutic fluoride agents and their administration during orthodontic therapy

Using daily fluoridated mouthrinses and toothpastes is one strategy the orthodontic patient can employ, to minimise white spot formation during orthodontic treatment. Other means available to the orthodontist to boost the fluoride exposure of enamel before and during orthodontic treatment have also been tested. These include:

- i. Fluoride containing etchants: Thornton et al (1986) examined enamel etched with phosphoric acid containing fluoride and concluded that no beneficial or protective effect was gained from this procedure.
- ii. Fluoride containing cements for banding: Wilson et al (1985) introduced the concept of the fluoride releasing potential of the glass ionomer cements. Glass ionomer cement, has been proven to release fluoride throughout its clinical life (Rezk-Lega et al 1991; Sadowsky et al 1983; Sadowsky et al 1981 and Scoville et al 1990). The glass ionomer cement was also found to be more reliable in band retention when compared to zinc phosphate cement (Fricker and McLachlan 1987; Maijer and Smith 1988; Mizrahi 1988 and Norris et al 1986). As such, today the glass ionomer cements are considered superior luting agents for orthodontic bands.

- iii. Fluoride containing bonding adhesives - Glass ionomer cement, when used as a bracket adhesive was found by Valk and Davidson (1987) to provide protection from decalcification to the adjacent enamel surfaces. The bond according to Mitchell (1992b), was however, weaker than the conventional composite bonding agents. Underwood et al (1989) and Sonis and Snell (1989) found fluoride containing composite resins provided both clinical effectiveness and caries inhibition through the release of fluoride. However, Fox (1990) and Mitchell (1992b) found little fluoride release and concluded that there was probably negligible therapeutic effect from this source.
- iv. Fluoride containing intraoral appliances: Corpron et al (1986) and Miethke and Newesely (1988) trialled devices specific for fluoride release and found *in vitro* studies promising.
- v. Fluoride containing elastomeric products: Joseph et al (1993) tested the fluoride release from elastic chain and concluded that for efficacy to be maintained, the chain should be replaced at weekly intervals. Mitchell (1992a) cites unpublished data on the *in vitro* fluoride release from elastomeric ties and reports an increase in the remineralisation of enamel with modules containing 10 per cent stannous fluoride as opposed to those containing 1.4 per cent stannous fluoride. The nature of the regular replacement of these modules throughout orthodontic treatment, is encouraging, due to the concept that low constant levels of fluoride may possibly be released at the site of greatest cariogenic challenge - the tooth/bracket margin.

2.3 Orthodontic Elastomeric Products

A polymer, according to Challa (1993) is a substance, the molecules of which are made up of many low molar mass units or monomer residues which are connected by primary bonds. Morton-Jones and Ellis (1986) further divided polymers into:

- i. Amorphous thermoplastics.
- ii. Semicrystalline thermoplastics.
- iii. Rubbers.

The polymers exhibiting typically elastic or rubbery behaviour are called elastomers. They may include natural and synthetic rubbers, thermoplastic rubbers, plasticised PVC and polyurethane elastomers.

According to Burford (1989), elastomers have three structural features:

- i. Long polymer chains with freely rotating links.
- ii. Low intermolecular forces.
- iii. A three dimensional network structure of interconnected polymer chains, usually joined by covalent cross-links.

The generic term "elastomer" describes materials which rapidly regain their original dimensions following periods of deformation. (Baty et al 1994)

2.3.1 Physical properties of elastomers

Elastomeric materials are, according to Seymour and Carraher (1984), high-molecular-weight polymers. They possess chemical and/or physical cross-linking in their structure. These cross-linked chains exist in a random geometric pattern when the elastomer is at rest.

Upon distortion the molecular chains unfold to an ordered linear fashion with the loss of some secondary bonds. The primary bonds remain cross-linked along the molecular chains unless the "elastic limit" of the material is exceeded, at which time the primary bonds are broken, and a permanent deformation of the elastomer occurs. If the elastic limit is not exceeded, the release of the elastomer extension results in the return to the passive configuration (Baty et al 1994) of the material - a feature called "elastic memory" (Seymour and Carraher 1984).

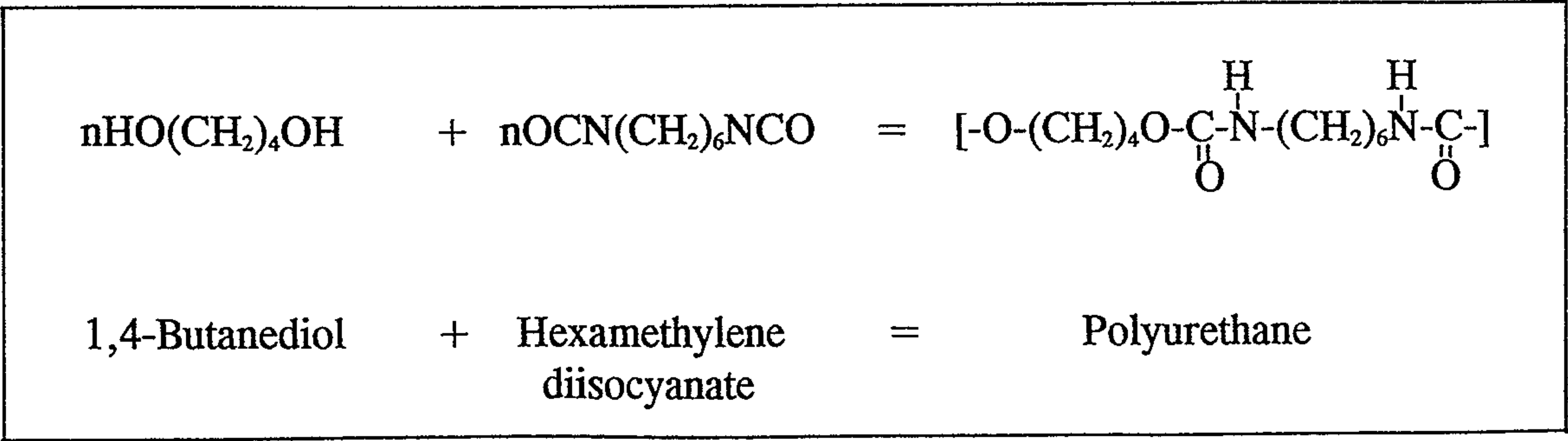
Specific details of the composition of orthodontic elastomers are not readily available, owing to the proprietary nature of the information regarding the manufacture of orthodontic elastomers. Hence the orthodontist has only a broad and generic perception of the chemical nature of elastomers.

2.3.2 Chemical composition of elastomers

The most commonly used elastic polymer in orthodontic products is most likely polyurethane rubber (Huget et al 1990) which broadly describes elastic polymers containing the urethane linkage.

Seymour and Carraher (1984) described polyurethane as being synthesised in a reaction of diisocyanate and diol or higher polyol. They describe a typical polyurethane as the result of the synthesis of 1, 4 - butanediol and hexamethylene diisocyanate (figure 1).

FIGURE 1



Such synthetic polymers are vulnerable to the exposure of free radicals, and as such, are best stored away from systems generating free radicals, such as ultraviolet radiation and ozone. The physical changes evidenced following such exposures include the loss of tensile strength and flexibility of the polymer.

2.3.3 Elastomers and their uses in orthodontic treatment

Elastomeric products have become significant in their variety of orthodontic uses following their introduction to dentistry products in the nineteen sixties. DeGenova et al (1985) listed the uses of elastomers in orthodontics as:

- i. The generation of light continuous forces for tooth retraction.
- ii. The closing of diastemas.
- iii. The correction of tooth rotations.
- iv. Arch constriction.

Elastomers are also used to provide space prior to the bonding of posterior teeth and to locate the position of the archwire in relation to the orthodontic bracket. This is achieved with small rounded elastomeric rings called "modules".

The elastomeric products in use in orthodontics have also been shown to have some undesirable qualities in the oral environment. Andreasen and Bishara (1970a and 1970b) showed that in an oral environment elastomeric products are prone to the absorption of water and saliva as well as the uptake of stains acquired from food and beverages.

The breakdown of the primary bonds during their extension in an oral environment also results in permanent deformation which manifests as the rapid loss of force due to stress relaxation. This loss of force results in the gradual loss of effectiveness of the elastomer and, according to Baty et al (1994), presents a dilemma to the clinician in their attempts to determine force levels operating on the dentition.

Ferriter et al (1990) in their investigation of force decay rates of elastomeric products, found that the rates were proportional to the pH of the oral environment and that pH levels above neutral resulted in a direct degradation of polyurethane chain elastics.

When elastomers were tested in environments of artificial saliva and topical fluorides, von Fraunhofer et al (1992) found that the elastic properties of the orthodontic chains diminished. Baty et al (1994), reported the relative increase in force degradation of the fluoride impregnated product when compared with the standard grey chain. However, Jefferies and von Fraunhofer (1991), when investigating a means of sterilising elastomers, found accelerated force degradation in chains that had been exposed to gluteraldehyde solution.

The recent incorporation of fluoride to the elastomeric chain was initiated with the aim of creating an "at source" release of fluoride for the prevention of enamel demineralisation during orthodontic treatment. Baty et al (1994) reported the work of Storie and von Fraunhofer (1992) in their findings of fluoride release from fluoride impregnated orthodontic chain. They found 3 mg of fluoride was released from a four-loop piece of chain in a three week testing period.

The incorporation of fluoride into elastomeric modules, theoretically means that a source of fluoride release is renewed with every change of modules for the orthodontic patient (approximately every 28 days).

The proven ability of fluoride to prevent demineralisation and enhance remineralisation of enamel has established it as a reliable therapeutic agent. Patients with an increased risk of enamel demineralisation benefit from a long-term, low concentration exposure to fluoride compounds.

Orthodontic patients display an increased need for enamel protection during fixed appliance therapy. Cements, varnishes, bonding agents and composites used in orthodontic treatment have delivered slow releasing fluoride to enamel surfaces in the past. The recent incorporation of fluoride into orthodontic elastomeric modules is the latest effort by manufacturers to deliver fluoride to the areas of greatest risk of enamel demineralisation.

To date, there have been no published studies reporting the release of fluoride from fluoride impregnated orthodontic elastomeric modules.

3.

MATERIALS AND METHOD

3.1

Materials

A total of 8 different types of orthodontic elastomeric modules were used in this study. Details of these products are given in Table 1.

TABLE 1

Details of orthodontic elastomeric modules (oem) used in this study.					
Supplier	Size	Material	Product Code	Fluoride (F) Non-Fluoride (NF)	Fluoride salt and concentration
"A"-COMPANY ¹ .	0.120	polyurethane	045 - 137	F	stannous and sodium fluoride: 1.5% by volume
"A"-COMPANY	0.110	polyurethane	045 - 136	F	stannous and sodium fluoride: 1.5% by volume
"A"-COMPANY	0.120	polyurethane	045 - 123	NF	---
"A"-COMPANY	0.110	polyurethane	045 - 122	NF	---
JOHN T. JENNINGS ² .	0.120	polyurethane and proprietary compounds	311 - 202	F	stannous fluoride 1.43% by volume
JOHN T. JENNINGS	0.110	polyurethane and proprietary compounds	311 - 102	F	stannous fluoride 1.43% by volume
JOHN T. JENNINGS	0.120	polyurethane and proprietary compounds	311 - 202	NF	---
JOHN T. JENNINGS	0.110	polyurethane and proprietary compounds	311 - 102	NF	---

1.
- "A"-Company : Patient Sticks, Trademark of "A"-Company Inc., a Johnson and Johnson Company (Figure 2).
2.
- John T. Jennings Pty. Ltd. - Orthodontic and General Dental Supplies, Sydney, Australia (Figure 3).

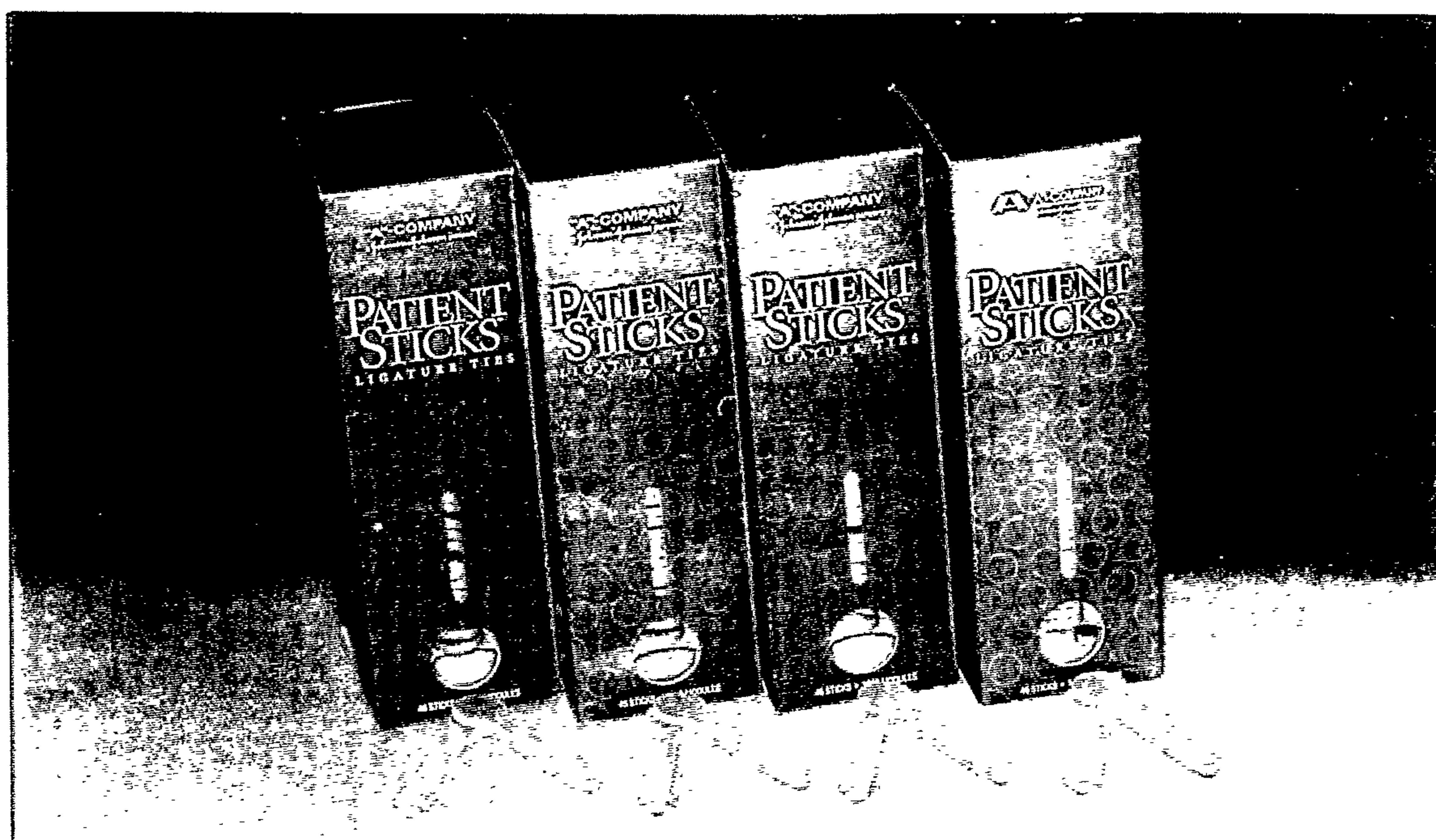


Figure 2: "A"-Company: "PATIENT STICKS".

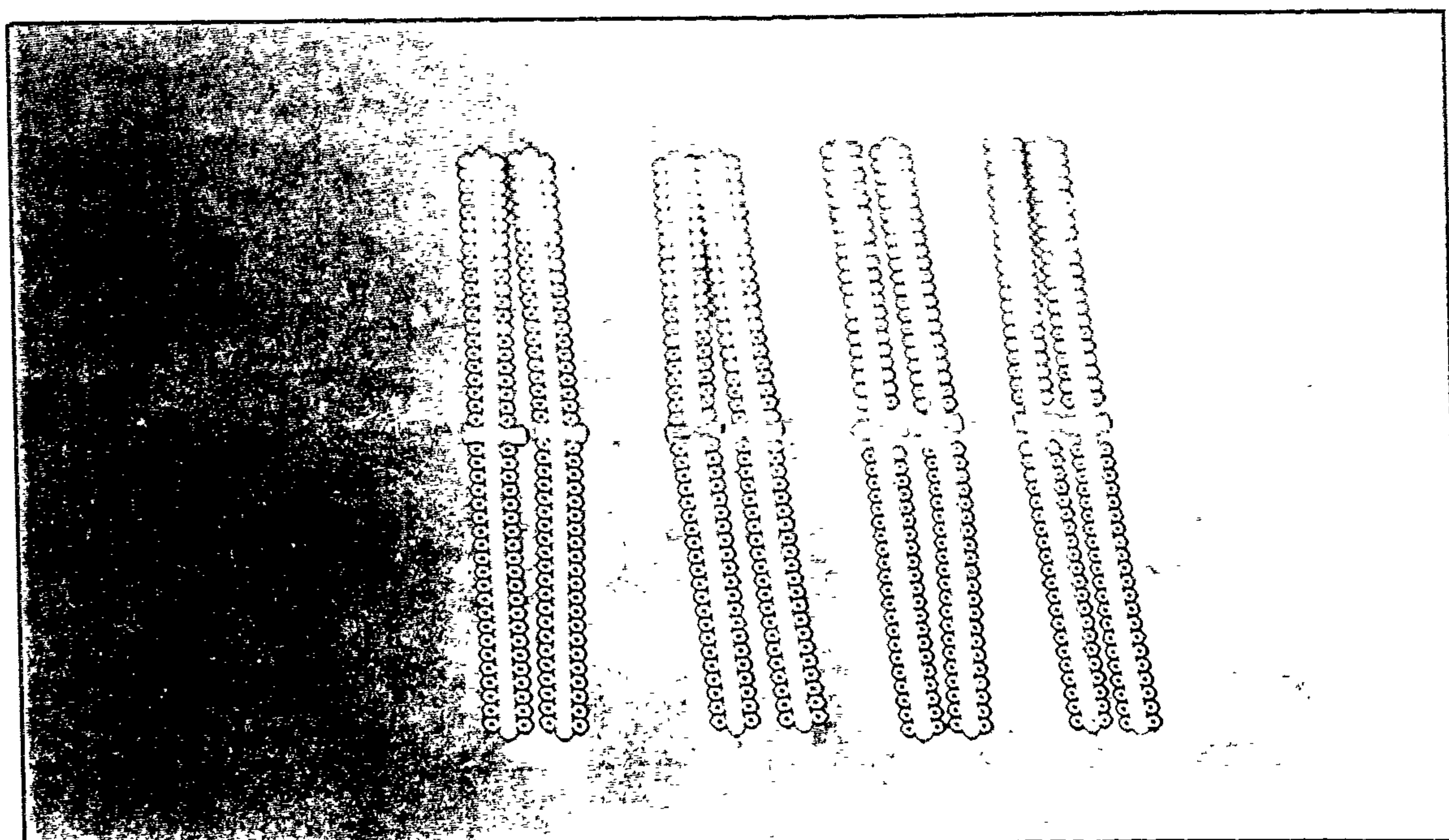


Figure 3: Orthodontic elastomeric modules supplied by John T. Jennings Pty. Ltd.

3.2 Method

The calibration of reproducibility of recordings of fluoride release from a randomly chosen sample of fluoride containing orthodontic elastomeric modules, is shown in Appendix 1.

3.2.1 Non-fluoride elastomeric modules

To avoid the possibility that fluoride was an unrecognised leachable constituent of the non-fluoride elastomeric modules, samples of these products were tested for fluoride release over a 28-day period. A sample of 100 modules from each of the 4 non-fluoride products shown in Table 1 was tested.

Each sample of 100 modules was divided into 5 groups of 20. Each group was then immersed in 4 ml of distilled-deionised water in a 5 ml polystyrene bottle (Disposable Products Pty. Ltd., Technology Park, Adelaide, Australia). The bottle was sealed and placed in an incubator (Qualtex Solidstat, Watson Victor Ltd., Sydney, Australia) at 37°C for 28 days (Figure 4). Fluoride levels were determined using the method described on pages 28-30.

The findings (Appendix 3) showed that there was negligible fluoride released. None of the bottles contained more than 1.3×10^{-6} MF⁻.

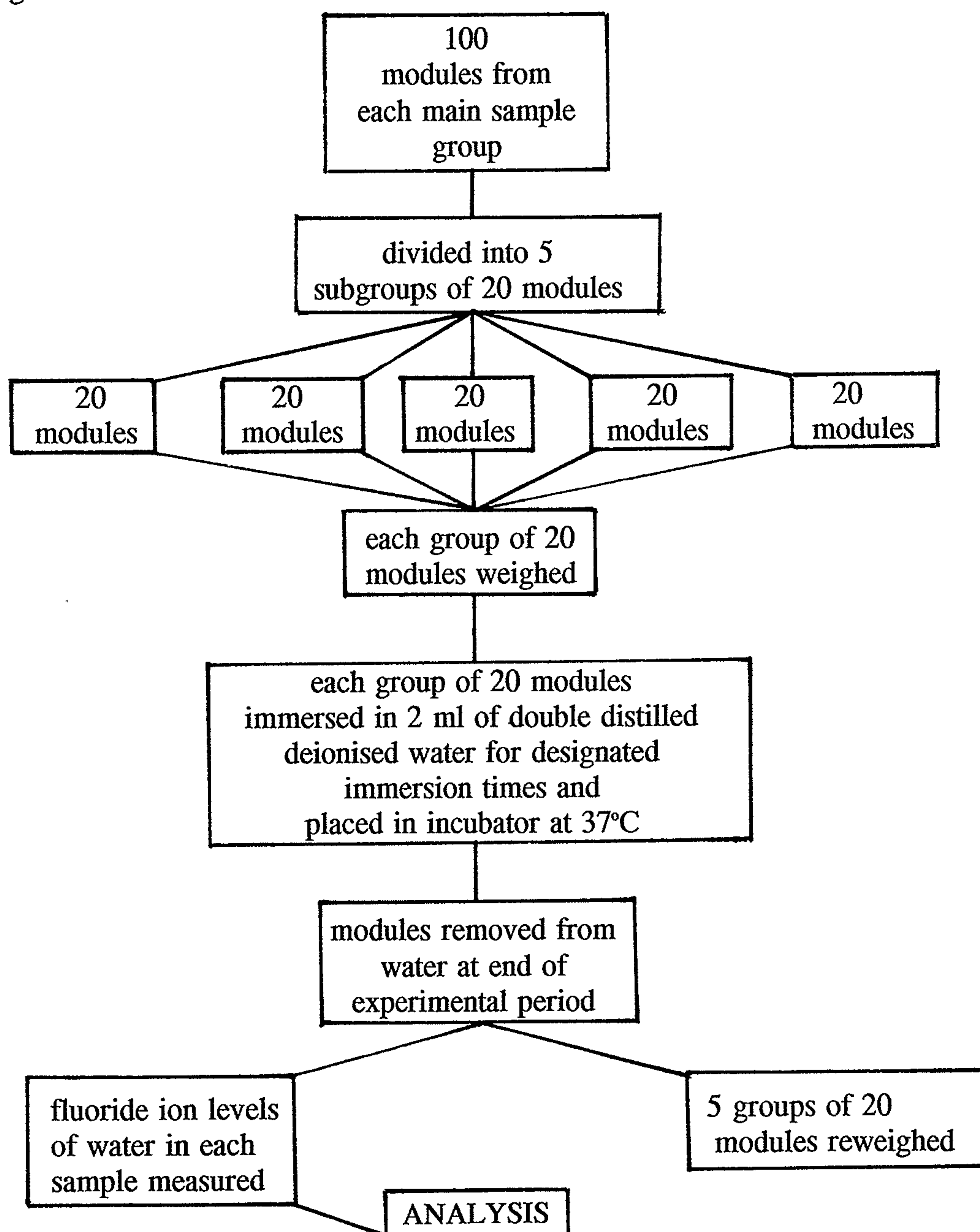
3.2.2 Fluoride elastomeric modules

In order to establish the parameters for the principal study a further sample of 100 modules from each of the 4 fluoride containing products in Table 1 was tested for fluoride release. The methodology was identical to that described above for the non-fluoride elastomeric modules. Again, each sample of 100 modules was divided into 5 groups of 20.

The results, shown in Appendix 3, indicate that there were detectable levels of fluoride released from all products. Furthermore, the final fluoride concentrations were such that the volume of water used in the main study could be reduced without the risk of saturated conditions occurring. The lesser volume also had the advantage of enhancing the sensitivity of the readings in situations where fluoride release levels may have been low.

3.3 Study Design

A flow diagram representing the study design used for the *in vitro* evaluation of fluoride containing elastomeric modules is shown below:



The five sample groups examined consisted of one control group (where only 2 ml of double-distilled deionised water was placed in each bottle) and 4 groups with the fluoride-impregnated materials. The designated code used in Appendix 3 is shown for each of the main sample groups is shown in Table 2.

TABLE 2

<u>GROUP</u>	<u>EXPERIMENTAL SAMPLE MATERIAL</u>
11	"A"-Company 0.110 fluoride elastomeric modules
12	"A"-Company 0.120 fluoride elastomeric modules
21	John T. Jennings 0.110 fluoride elastomeric modules
22	John T. Jennings 0.120 fluoride elastomeric modules
3	Control - 2 ml double distilled deionised water only

The study design was primarily based on the procedure used by Wilson et al (1985) to assay fluoride release from glass ionomer cements.

3.3.1 Procedure

Prior to use all plastic ware used in the experiment was washed in 1:3 HCl, then rinsed 10 times in distilled deionised water and finally dried, in an oven at 37°C for 15 hours.

After weighing, each sub-group of 20 modules was placed in a 5 ml polystyrene bottle with a screw cap (Disposable Products Pty. Ltd., Technology Park, Adelaide, Australia) containing 2 ml of double distilled deionised water. The cap was sealed with self adhesive teflon tape. The sealed bottles containing the modules were placed in an incubator (Qualtex Solidstat, Watson Victor Ltd., Sydney, Australia) at 37°C for the appropriate exposure period (Figure 4).

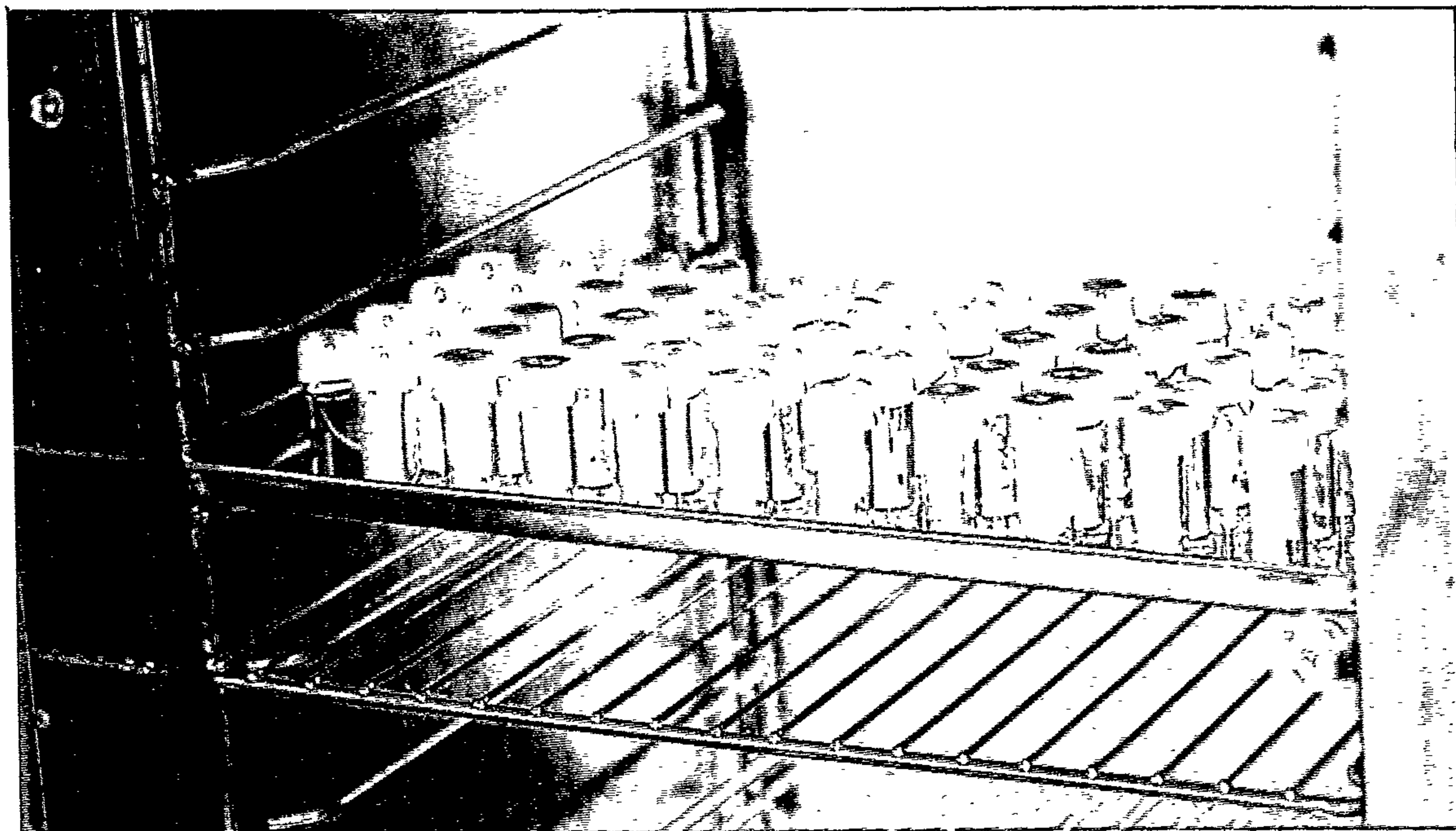


Figure 4: Qualtex Incubator and samples.

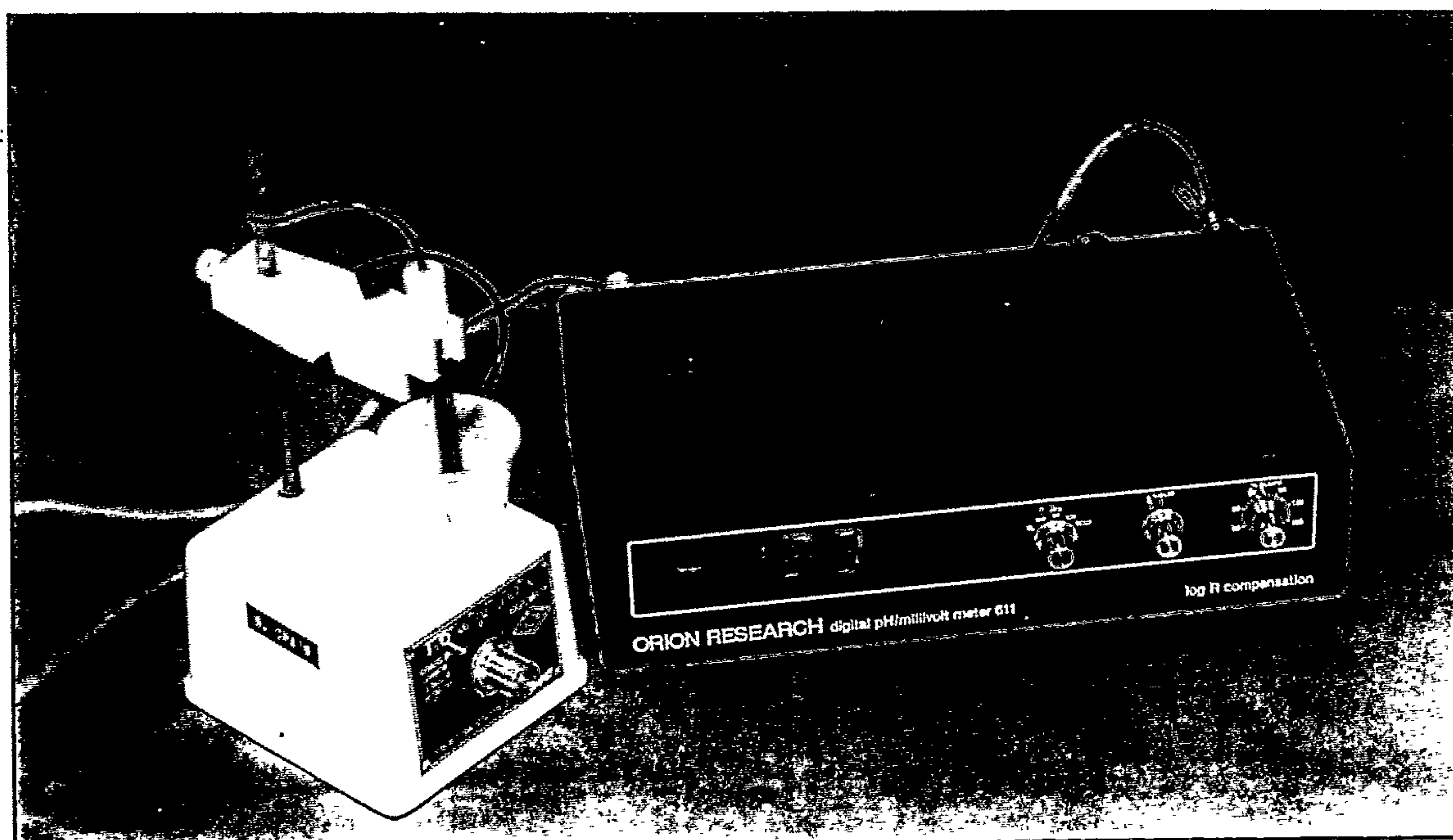


Figure 5: Orion fluoride electrode and Phillips digital pH-meter

Each sub-group of 20 modules was immersed sequentially in a series of seven 2 ml solutions to give total immersion times of 24 hours, 48 hours, 72 hours, 240 hours (10 days), 408 hours (17 days), 576 hours (24 days) and 744 hours (31 days).

Following removal of the modules from a bottle at the end of an immersion period the bottle was again sealed and stored in a refrigerator at 4°C awaiting fluoride analysis of the contents.

Before fluoride analysis, the contents of each bottle were brought to room temperature (21 +/- 1°C)

Fluoride analysis was performed with a combination fluoride ion electrode (Orion Model 9606-00, Orion Research Inc., Boston, USA) connected to a digital pH meter (Phillips model PW9409, Phillips, The Netherlands) (Figure 5).

The electrode was calibrated using known standards of fluoride ion. Dilutions were made from a standard 0.1 M/LF⁻ solution (Orion 940906 Orion Research Inc. Boston, USA). Each aliquot was diluted 1:1 with TISAB II with CDTA (Orion 940909, Orion Research Inc. Boston, USA)) prior to the electrode readings being performed.

Both the fluoride standard and the TISAB II solutions were obtained through Linbrook Industrial Pty. Ltd., Thornleigh, NSW, Australia.

3.4 Principal Study Analysis

The data obtained from the principal study was subjected to an analysis of variance (ANOVA). This examined the results for differences when the parameters of brand, size, brand and size, time, brand and time, size and time and finally brand, size and time, were compared.

The data was further subjected to a Student-Newman-Keul test for multiple comparisons, which sought to group the results over various time sequences with respect to the rate and amount of fluoride release.

4.

RESULTS

The weights of the modules before and after immersion in double distilled deionised water for 744 hours are shown in Appendix 2. All sub-groups of modules showed a loss of mass during the experiment. The differences in weight change ranged from -2.4 to -6.2 percent.

4.1

Total Fluoride Ion Release

The experimental control samples of double distilled deionised water exhibited negligible fluoride ion levels of $1.05 \times 10^{-6} \text{ MF}^-$ or less and were deemed fluoride free for the purposes of this evaluation.

The data based on the fluoride ion release measured from "A"-Company 0.110 and 0.120 and John T. Jennings 0.110 and 0.120 fluoride impregnated orthodontic elastomeric modules and are presented in raw and cumulative forms in Appendix 4 and analysed in the cumulative form in Figure 6 and Table 3.

TABLE 3

Cumulative total fluoride ion release: means and standard deviations (micrograms of fluoride/module, initial dry weight)								
Sample Group n=5	A-Company 0.110		A-Company 0.120		John Jennings 0.110		John Jennings 0.120	
	Mean	sd	Mean	sd	Mean	sd	Mean	sd
24 hours	1.119	0.0821	1.250	0.702	0.825	0.042	0.363	0.000
48 hours	1.408	0.199	1.711	0.117	1.164	0.500	0.452	0.000
72 hours	1.601	0.219	1.966	0.141	1.371	0.047	0.505	0.016
240 hours	1.949	0.258	2.400	0.210	1.931	0.099	0.603	0.246
408 hours	2.118	0.275	2.661	0.258	2.605	0.199	0.702	0.084
576 hours	2.202	0.280	2.772	0.275	2.988	0.274	0.784	0.138
744 hours	2.242	0.292	2.833	0.286	3.227	0.269	0.844	0.177

Fluoride Ion Release from Orthodontic Elastomeric Modules between 0 and 744 Hours (0 and 31 days)

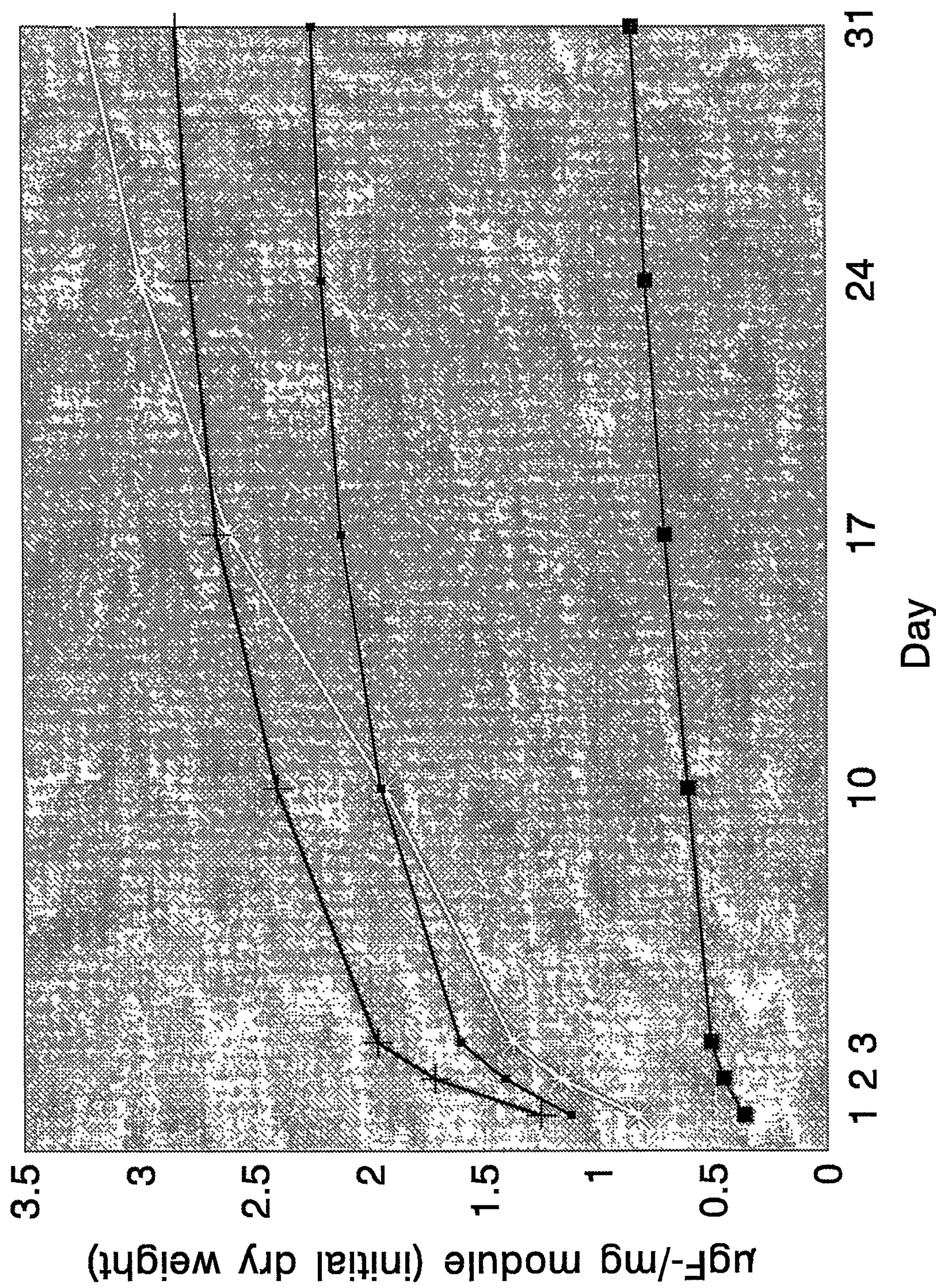


Figure 6

Figure 6 shows the total amount and relative rate of release of microgram fluoride ion per milligram of initial dry weight of the elastomeric modules, over the 744 hour (31 day) experimental period.

All brands displayed an initial (3 day) burst of fluoride release, followed by a constant, but low, fluoride release over the remaining 28 days.

The John T. Jennings 0.120 modules showed the lowest level of initial ($0.363 \mu\text{gF}^-$) of fluoride release at day 1, while "A"-Company 0.120 modules displayed the highest day 1 level of fluoride, ($1.250 \mu\text{gF}^-$).

The "A"-Company 0.110 and 0.120 demonstrated the most similar pattern of fluoride release while the John T. Jennings 0.110 and 0.120 brands showed the greatest divergence in release of fluoride ions.

4.2 Rate of Fluoride Ion Release

The rate of fluoride ion released from the four groups over the experimental period, was examined in total and over designated time periods.

An analysis of the fluoride ion releasing pattern of the four module groups, was expressed over the time intervals; i. 0 - 72 hours; ii. 72 - 744 hours; and iii. 0 - 744 hours, and is represented in Figure 7.

Figure 7 shows that relative to their total release (0 - 744 hours), all products except the John T. Jennings 0.110 modules released a greater amount of fluoride ion in the first 72 hours of the experimental period, than in the subsequent 72 - 744 hour (3 - 31 day) period. This result indicates the principal fluoride release appears to occur early in the experimental period. The result expressed in Figure 8 confirms this trend.

Fluoride Ion Release from Orthodontic Elastomeric Modules at Three Designated Times Intervals

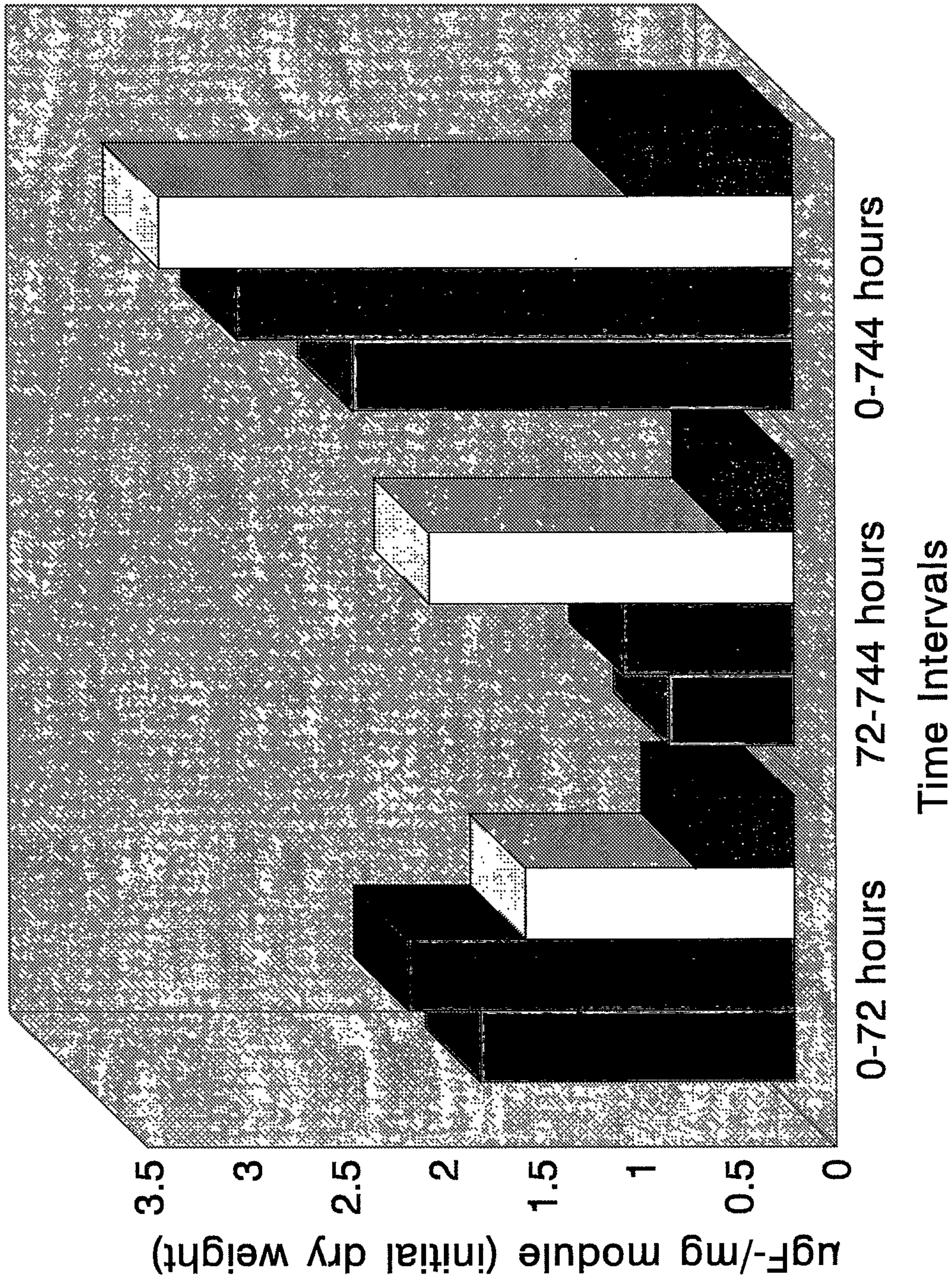


Figure 8 shows the profile of the percentage of total fluoride ion release over 744 hours (31 days) for the "A"-Company 0.110 and 0.120 and John T. Jennings 0.110 and 0.120 modules.

The John T. Jennings 0.110 modules show a 40% release of total fluoride released during the 31 day study, after three days. All other brands, show a 60% minimum release of the total fluoride over the first three days.

At day 10 (240 hours), both "A"-Company brands had released at least 80% of their total fluoride release, where John T. Jennings 0.110 and 0.120 had released 50% and 70% of their total fluoride release, respectively. The day 10 (240 hour) absolute levels of fluoride release are represented in Figure 9.

Figure 8 indicates that all four brands had released over 90% of their total fluoride release at day 24 (576 hours) and that relatively minimal release of fluoride ion occurred for each brand tested, in the final 7 days of the experimental period.

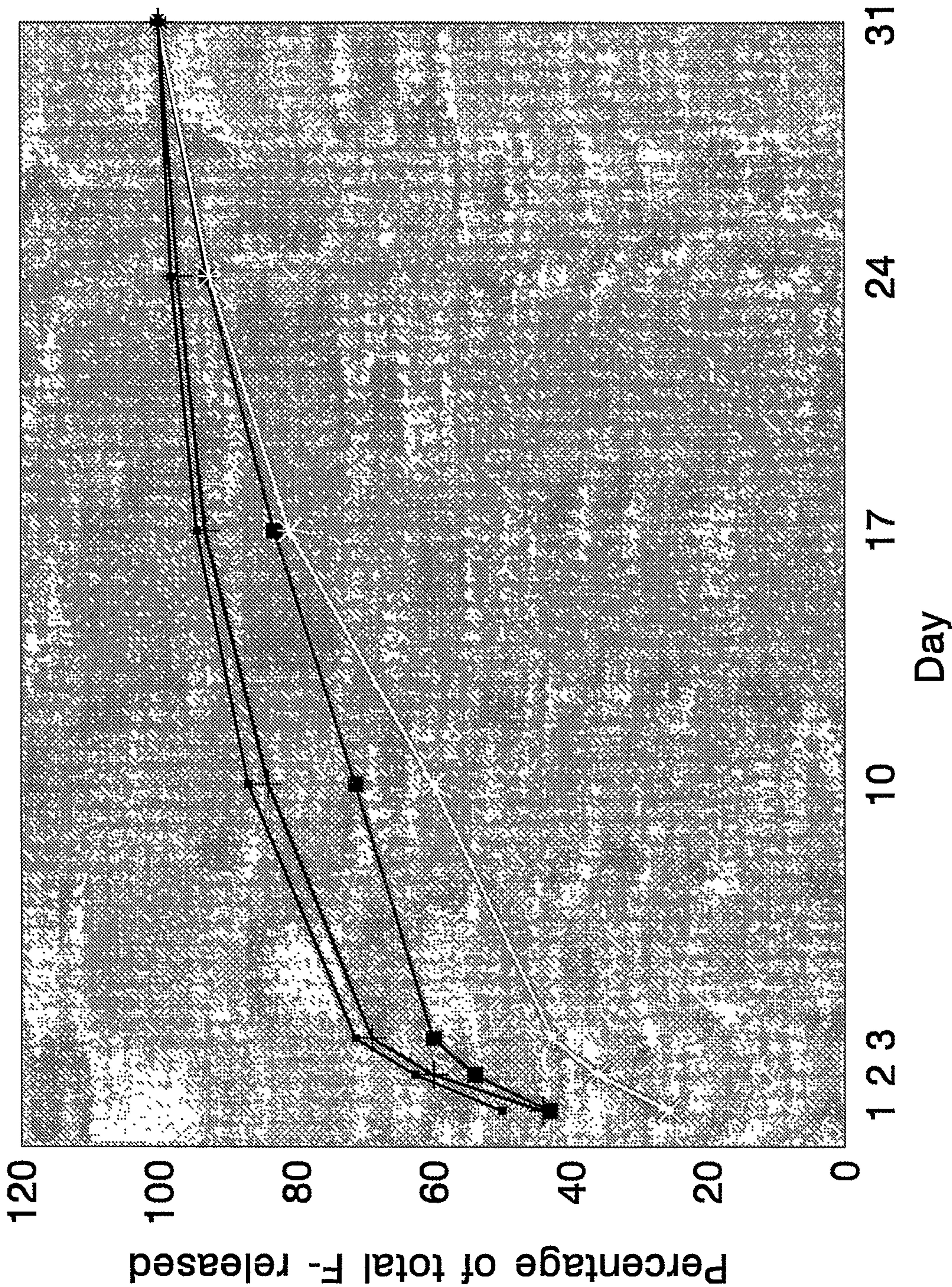
4.3 Statistical Analysis

An analysis of variance (ANOVA) and the Student-Newman-Keul test were used to statistically analyse the data.

4.3.1 The analysis of variance (ANOVA)

To examine the results of the study for statistical differences in the parameters of brand, size, brand and size, time; brand and time, size and time and brand, size and time, an ANOVA was employed (Appendix 5). The ANOVA showed that each experimental group displayed highly significant F-values when all combinations of the variables of product brand, module size and time intervals were considered.

Percentage of Total Fluoride Ion Released from Orthodontic Elastomeric Modules between 0 and 744 Hours (0 and 31 days)



→ A-Company 0.110 + A-Company 0.120 ■ J. Jennings 0.120

Total Fluoride Ion Release from Orthodontic Elastomeric Modules at 240 Hours



Figure 9

This means that the probability of the events observed and recorded in the experiment occurring by chance is virtually non-existent and verifies that the events and readings observed occurred due to the nature of the product. Therefore, it can be concluded, the fluoride levels released can be considered directly attributable to the fluoride releasing potential of the product tested. The four products tested also showed a strong statistical evidence of difference in fluoride releasing potential between each group. Thus each brand showed independent statistical significance when the ANOVA was applied.

4.3.2 Student-Newman-Keul test (multiple comparisons)

A Student-Newman-Keul test (Appendix 5 and Appendix 6) was used to examine the possibility of grouping of results within the data.

The data of various experimental groups coincided at the following times:

- i. At 408 and 576 hours, the fluoride-release levels of the A-Company 0.120 and John Jennings 0.110 cumulative totals were statistically coincident.
- ii. When grouped over three time periods, the A-Company 0.110 and John Jennings 0.110 modules were statistically coincident in their fluoride-release levels between 0 and 72 hours.
- iii. The A-Company 0.110 and 0.120 modules were statistically coincident in their fluoride-release levels between the 72 and 744 hour time divisions.

These results are represented graphically in Figure 6 and Figure 7.

5. DISCUSSION

In the experiment described in this thesis, the amounts and rates of fluoride release from four brands of fluoride impregnated commercially available orthodontic elastomeric modules were examined. Two modules (0.110 and 0.120) were tested from two suppliers, "A"-Company, (Johnson and Johnson) and John T. Jennings, Australia.

All four products used in this study contained stannous fluoride, although the "A"-Company products contained a mixture of stannous fluoride and sodium fluoride. The relative concentrations of these two salts are not known.

All fluoride impregnated modules that were tested, released fluoride. The greatest mean fluoride release over the 31 day testing period was demonstrated by the John T. Jennings supplied 0.110 module, followed in decreasing order, by the "A"-Company 0.120, the "A"-Company 0.110 and, finally, the John T. Jennings 0.120 modules.

Both "A"-Company products showed an accelerated rate of fluoride release in the first 72 hours of the testing period. This rate then plateaued from 72 to 744 hours (3 - 31 days). The John T. Jennings 0.120 modules showed a similar fluoride release pattern. However, the 0.110 modules from John T. Jennings showed a greater absolute amount of fluoride release between 72 and 744 hours (3 - 31 days) compared to the initial 0 to 72 hours (0 - 3 days) time period.

The total fluoride release expressed as a percentage over the 31 day testing period showed that, at the tenth day, at least, 50% of the total fluoride release had been recorded from each of the four samples tested. It was further noted that by the seventeenth day, at least 80% of the total fluoride release had been observed. The final 20% of fluoride release from each module group tested occurred between the eighteenth and the thirty-first day. The differences in fluoride release at each time interval, and between each product in this experiment, were found to be statistically significant.

These results are similar to those found by Joseph et al (1993). In their *in vitro* study of fluoride impregnated power chain, they found that the initial rate of fluoride release from the chain was very high but this dropped to very low levels after one week. They suggested from this finding that the reservoir of the fluoride had probably been exhausted after one week.

The profile of fluoride release for these elastomeric products is similar to the fluoride release shown in previous studies of other fluoride impregnated dental materials. In his 1991 study of the fluoride release of adhesive bonding resins, Duncan showed that there was an initial burst of fluoride release followed by a steady decline over the following twelve weeks. Similarly, Wilson et al (1985) noted a comparable situation with fluoride release from glass ionomer cements.

The reasons for the differences in the fluoride releasing properties of the four different elastomeric orthodontic module brands used in this study are not known. For example, the John Jennings 0.120 elastomeric modules released only 30 percent of the fluoride leached from the "A"-Company 0.120 modules over a 31 day period.

Undoubtedly such factors as the porosity of the modules in water and the availability of fluoride binding sites within the modules influence the rate and total amount of fluoride released.

For the modules to be beneficial over a 30 day period presumably there would have to be some residual effect from the "fluoride burst" seen in the first 10 days. Conceivably there could be some fluoride uptake in the surrounding enamel, and the fluoride as well as the tin moieties, could have a distinct antibacterial effect on organisms in accumulated plaque. The tin (stannous) moiety from stannous fluoride possesses very definite antimicrobial properties (Yost and Van De Mark 1987).

Zapski (1971), in an *in vivo* study of 25 orthodontic patients, showed that the continuous wearing of stannous fluoride impregnated elastics reduced the salivary *Streptococcus salivarius* count. Patients in this study displayed a 6 percent increase in the mean fluoride concentration of saliva over the two week period of the study.

The theory behind incorporating fluoride into elastomeric modules is sound. The elastomeric modules, and hence the availability of fluoride, are located in close proximity to the tooth/bracket margin, which is the most frequent site of enamel demineralisation in orthodontic patients. The fluoride releasing potential of these modules is recharged due to their replacement on a four weekly cycle during orthodontic treatment. This results in the elastomeric modules being ideally suited as reservoirs of long term low concentration fluoride release for the orthodontic patient.

Fluoride containing elastomeric modules have the promise of being a useful adjunct to the current fluoride regimen used for orthodontic patients. Their use could supplement:

- i. Thorough oral hygiene and dietary instruction, provided by the orthodontist, at the beginning of treatment, to the orthodontic patient (Harvey and Powell 1981).
- ii. Periodic professional oral hygiene instruction and maintenance as advocated by Artun and Brobakken (1986) and Lundstrom (1980).
- iii. Plaque controlling therapeutic home mouthrinsing programs, such as those using chlorhexidine and reported by Hogg (1990).
- iv. The use of regular topical fluoride applications throughout fixed appliance therapy (Shannon 1981).
- v. The daily home use of fluoride containing toothpaste used in conjunction with a low concentration (0.05% sodium fluoride) commercially available mouthrinse, as recommended by O'Reilly and Featherstone (1987).

- vi. The orthodontist's choice of fluoride releasing materials, such as; glass ionomer cements for molar band cementation (Wilson et al 1985), fluoride releasing bonding resins (Duncan 1991) and fluoride impregnated elastomeric chains (Joseph et al 1993).
- vii. The removal of plaque retaining excess composite flash, from the tooth/bracket margin (Mitchell 1992a).

As this study was concerned with *in vitro* release of fluoride from the elastomeric modules in an aqueous environment, *in vivo* studies will provide a total picture of the clinical efficacy of these products. Therefore, future clinical trials will indicate the clinical benefit of fluoride release from elastomeric orthodontic modules.

6.

CONCLUSIONS

The hypothesis that the fluoride ion is released from four proprietary brands of orthodontic elastomeric module *in vitro*, has been confirmed.

The following conclusions can be drawn from the findings of this study:

- i. There is a statistically significant difference in the ability of the four proprietary brands tested, to release fluoride in an aqueous environment.
- ii. Fluoride is released from all products in an "initial burst" and then subsequently tapers off over a 21 day period.
- iii. Despite the similarities of the type and concentrations of the fluoride salts used in the elastomeric modules, it is seen that the rate of fluoride release can differ.
- iv. Orthodontic elastomeric modules may be a very useful vehicle for fluoride delivery during fixed appliance therapy.

In view of the fact that all four brands tested had released at least 50% of the fluoride ion released in the total experiment, at the tenth day, it is concluded that the incorporation of fluoride into the separating elastomeric rings, used prior to band placement may be warranted. A seven to ten day exposure of enamel to a slow release of fluoride prior to band placement could be beneficial.

Following the encouraging results of this study, it is concluded that long term *in vivo* studies should be undertaken.

APPENDIX 1

REPRODUCIBILITY OF RECORDINGS OF FLUORIDE RELEASE FROM
FLUORIDE CONTAINING ORTHODONTIC ELASTOMERIC MODULES

CALIBRATION SAMPLE: Bottle Number : 2
 Brand : 2
 Size : 1
 Time : 1

Calibration Reading Number	mV Reading	Molarity	µgF/module
1	-63	1.8 x 10 ⁻³	0.796
2	-63	1.8 x 10 ⁻³	0.796
3	-63	1.8 x 10 ⁻³	0.796
4	-63	1.8 x 10 ⁻³	0.796
5	-63	1.8 x 10 ⁻³	0.796

APPENDIX 2

PRE AND POST EXPERIMENT WEIGHTS OF PRINCIPAL STUDY MODULES

Sample	Pre-Weight (g)	Post-Weight (g)	Difference (g)	% Difference
"A"-Company 0.110				
1	0.0769	0.0721	-0.0048	-6.2
2	0.0760	0.0723	-0.0037	-4.9
3	0.0762	0.0724	-0.0038	-5.0
4	0.0761	0.0724	-0.0037	-4.9
5	0.0750	0.0732	-0.0018	-2.4
"A"-Company 0.120				
1	0.0845	0.0804	-0.0041	-4.8
2	0.0820	0.0781	-0.0039	-4.7
3	0.0783	0.0740	-0.0043	-5.5
4	0.0873	0.0821	-0.0052	-5.9
5	0.0847	0.0805	-0.0042	-4.9
John T. Jennings 0.110				
1	0.0867	0.0823	-0.0044	-5.1
2	0.0859	0.0816	-0.0043	-5.0
3	0.0852	0.0804	-0.0048	-5.6
4	0.0867	0.0822	-0.0045	-5.2
5	0.0861	0.0821	-0.0040	-4.6
John T. Jennings 0.120				
1	0.0897	0.0860	-0.0037	-4.1
2	0.0934	0.0896	-0.0038	-4.1
3	0.0959	0.0919	-0.0040	-4.2
4	0.0922	0.0884	-0.0038	-4.1
5	0.0946	0.0911	-0.0035	-4.0

APPENDIX 3

SECTION ONE

Comparison of 28 day fluoride release from fluoride and non-fluoride impregnated orthodontic elastomeric modules.

Definitions:

i. Bottle Number:

Each sample group consisted of 5 bottles numbered 1 - 5. Each bottle contained 4mls of double distilled deionised water and 20 elastomeric modules.

ii. Brand:

Manufacturers brands were coded:

A-Company	= 1
John Jennings	= 2
Control group	= 3

iii. Size:

0.110 modules	= 1
0.120 modules	= 2

iv. Type:

Fluoride impregnated	= 1
Non-Fluoride impregnated	= 2

v. "NFLR": Negligible fluoride levels recorded (less than 1.3×10^{-6} MF⁻)

NON-FLUORIDE ELASTOMERIC MODULE STUDY RESULTS

Bottle Number	Brand	Size	Type	mV Reading	µgF/Module	Sample Group Mean	Standard Deviation
1	1	1	2	162	NFLR		
2	1	1	2	162	NFLR		
3	1	1	2	161	NFLR		
4	1	1	2	161	NFLR		
5	1	1	2	163	NFLR		
1	1	2	2	168	NFLR		
2	1	2	2	163	NFLR		
3	1	2	2	164	NFLR		
4	1	2	2	163	NFLR		
5	1	2	2	162	NFLR		
1	2	1	2	160	NFLR		
2	2	1	2	161	NFLR		
3	2	1	2	162	NFLR		
4	2	1	2	159	NFLR		
5	2	1	2	160	NFLR		
1	2	2	2	143	NFLR		
2	2	2	2	151	NFLR		
3	2	2	2	154	NFLR		
4	2	2	2	154	NFLR		
5	2	2	2	156	NFLR		
1	3	-	-	146	NFLR		
2	3	-	-	150	NFLR		
3	3	-	-	153	NFLR		
4	3	-	-	152	NFLR		
5	3	-	-	155	NFLR		

FLUORIDE ELASTOMERIC MODULES STUDY RESULTS

1	1	1	1	-41	7.41		
2	1	1	1	-43	7.98		
3	1	1	1	-43	7.98		
4	1	1	1	-43	7.98		
5	1	1	1	-43	7.98	7.866	0.228
1	1	2	1	-53	12.16		
2	1	2	1	-47	9.54		
3	1	2	1	-56	13.68		
4	1	2	1	-48	10.26		
5	1	2	1	-53	12.16	12.39	1.53
1	2	1	1	-65	19.00		
2	2	1	1	-60	15.96		
3	2	1	1	-52	11.40		
4	2	1	1	-61	15.96		
5	2	1	1	-62	16.72	15.808	2.76
1	2	2	1	-19	3.04		
2	2	2	1	-20	3.24		
3	2	2	1	-27	4.18		
4	2	2	1	-27	4.18		
5	2	2	1	-27	4.18	3.7628	0.577

APPENDIX 4

PRINCIPAL STUDY

Fluoride release from fluoride impregnated orthodontic elastomeric modules.

Definitions:

i. Bottle Number:

Each sample group consisted of 5 bottles numbered 1 - 5. Each bottle contained 2mls of double distilled deionised water and 20 elastomeric modules.

ii. Brand:

Manufacturers brands were coded:

A-Company	= 1
John Jennings	= 2
Control group	= 3

iii. Size:

0.110 modules	= 1
0.120 modules	= 2

iv. Time Intervals:

24 Hours	= 1
48 Hours	= 2
72 Hours	= 3
240 Hours	= 4
408 Hours	= 5
576 Hours	= 6
744 Hours	= 7

v. "NFLR": Negligible fluoride levels recorded (less than 1.05×10^{-6} MF⁻)

PRINCIPAL STUDY RESULTS

Bottle Number	Brand	Size	Time	mV Reading	µgF/Module (initial dry weight)	Cumulative Total	Sample Group Mean	Standard Deviation
1	1	1	1	-67	1.037	1.037		
2	1	1	1	-70	1.200	1.200		
3	1	1	1	-66	1.047	1.047		
4	1	1	1	-68	1.098	1.098		
5	1	1	1	-70	1.216	1.216	1.119	0.0821
1	1	1	2	-37	0.345	1.382		
2	1	1	2	-40	0.370	1.570		
3	1	1	2	-38	0.339	1.081		
4	1	1	2	-38	0.339	1.437		
5	1	1	2	-39	0.354	1.570	1.408	0.199
1	1	1	3	-21	0.168	1.550		
2	1	1	3	-26	0.210	1.780		
3	1	1	3	-21	0.169	1.250		
4	1	1	3	-24	0.194	1.631		
5	1	1	3	-28	0.222	1.792	1.601	0.219
1	1	1	4	-39	0.345	1.895		
2	1	1	4	-42	0.375	2.155		
3	1	1	4	-35	0.299	1.549		
4	1	1	4	-37	0.319	1.950		
5	1	1	4	-43	0.405	2.197	1.949	0.258
1	1	1	5	-21	0.172	2.067		
2	1	1	5	-26	0.210	2.365		
3	1	1	5	-15	0.134	1.683		
4	1	1	5	-21	0.174	2.124		
5	1	1	5	-18	0.152	2.349	2.118	0.275
1	1	1	6	-8	0.098	2.165		
2	1	1	6	-6	0.095	2.460		
3	1	1	6	3	0.064	1.747		
4	1	1	6	-2	0.079	2.203		
5	1	1	6	-3	0.086	2.435	2.202	0.280
1	1	1	7	12	0.046	2.211		
2	1	1	7	10	0.050	2.510		
3	1	1	7	24	0.028	1.775		
4	1	1	7	16	0.039	2.242		
5	1	1	7	21	0.036	2.471	2.242	0.292
1	1	2	1	-72	1.214	1.214		
2	1	2	1	-73	1.251	1.251		
3	1	2	1	-74	1.358	1.358		
4	1	2	1	-75	1.262	1.262		
5	1	2	1	-74	1.166	1.166	1.250	0.702
1	1	2	2	-42	0.359	1.573		
2	1	2	2	-51	0.509	1.760		
3	1	2	2	-48	0.485	1.843		
4	1	2	2	-50	0.478	1.740		
5	1	2	2	-49	0.471	1.637	1.711	0.117

PRINCIPAL STUDY RESULTS

Bottle Number	Brand	Size	Time	mV Reading	µgF/Module (initial dry weight)	Cumulative Total	Sample Group Mean	Standard Deviation
1	1	2	3	-31	0.233	1.806	1.966	0.141
2	1	2	3	-34	0.268	2.028		
3	1	2	3	-36	0.300	2.143		
4	1	2	3	-36	0.269	2.009		
5	1	2	3	-28	0.206	1.843		
1	1	2	4	-43	0.359	2.165	2.400	0.210
2	1	2	4	-53	0.556	2.584		
3	1	2	4	-49	0.485	2.628		
4	1	2	4	-46	0.391	2.400		
5	1	2	4	-45	0.381	2.224		
1	1	2	5	-27	0.197	2.362	2.661	0.258
2	1	2	5	-41	0.342	2.926		
3	1	2	5	-36	0.291	2.919		
4	1	2	5	-33	0.243	2.643		
5	1	2	5	-32	0.233	2.457		
1	1	2	6	-11	0.103	2.465	2.772	0.275
2	1	2	6	-17	0.139	3.065		
3	1	2	6	-11	0.116	3.035		
4	1	2	6	-13	0.108	2.751		
5	1	2	6	-6	0.085	2.542		
1	1	2	7	9	0.047	2.512	2.833	0.286
2	1	2	7	-3	0.078	3.143		
3	1	2	7	2	0.067	3.102		
4	1	2	7	0	0.065	2.816		
5	1	2	7	7	0.051	2.593		
1	2	1	1	-66	0.876	0.876	0.825	0.042
2	2	1	1	-63	0.796	0.796		
3	2	1	1	-65	0.847	0.847		
4	2	1	1	-65	0.832	0.832		
5	2	1	1	-61	0.772	0.772		
1	2	1	2	-41	0.328	1.204	1.164	0.500
2	2	1	2	-41	0.331	1.127		
3	2	1	2	-43	0.367	1.214		
4	2	1	2	-42	0.341	1.173		
5	2	1	2	-41	0.331	1.103		
1	2	1	3	-28	0.197	1.401	1.371	0.047
2	2	1	3	-29	0.203	1.33		
3	2	1	3	-29	0.205	1.419		
4	2	1	3	-31	0.219	1.392		
5	2	1	3	-30	0.211	1.314		
1	2	1	4	-56	0.591	1.992	1.931	0.099
2	2	1	4	-52	0.508	1.838		
3	2	1	4	-53	0.535	1.954		
4	2	1	4	-58	0.657	2.049		
5	2	1	4	-52	0.507	1.821		

PRINCIPAL STUDY RESULTS

Bottle Number	Brand	Size	Time	mV Reading	µgF/Module (initial dry weight)	Cumulative Total	Sample Group Mean	Standard Deviation
1	2	1	5	-59	0.679	2.671		
2	2	1	5	-56	0.597	2.435		
3	2	1	5	-54	0.557	2.511		
4	2	1	5	-64	0.876	2.925		
5	2	1	5	-58	0.662	2.483	2.605	0.199
1	2	1	6	-43	0.350	3.021		
2	2	1	6	-41	0.331	2.766		
3	2	1	6	-42	0.334	2.845		
4	2	1	6	-50	0.525	3.450		
5	2	1	6	-44	0.375	2.858	2.988	0.274
1	2	1	7	-30	0.210	3.231		
2	2	1	7	-32	0.238	3.004		
3	2	1	7	-31	0.231	3.076		
4	2	1	7	-32	0.236	3.686		
5	2	1	7	-37	0.282	3.140	3.227	0.269
1	2	2	1	-44	0.360	0.360		
2	2	2	1	-45	0.366	0.366		
3	2	2	1	-45	0.356	0.356		
4	2	2	1	-45	0.370	0.370		
5	2	2	1	-45	0.361	0.361	0.363	0.010
1	2	2	2	-7	0.083	0.443		
2	2	2	2	-9	0.085	0.451		
3	2	2	2	-8	0.079	0.435		
4	2	2	2	-13	0.103	0.473		
5	2	2	2	-12	0.096	0.457	0.452	0.013
1	2	2	3	6	0.050	0.493		
2	2	2	3	1	0.058	0.509		
3	2	2	3	4	0.051	0.486		
4	2	2	3	2	0.057	0.530		
5	2	2	3	4	0.052	0.509	0.505	0.016
1	2	2	4	-10	0.093	0.586		
2	2	2	4	-11	0.093	0.602		
3	2	2	4	-12	0.095	0.581		
4	2	2	4	-16	0.115	0.645		
5	2	2	4	-11	0.092	0.601	0.603	0.246
1	2	2	5	0	0.063	0.649		
2	2	2	5	-7	0.081	0.683		
3	2	2	5	-5	0.071	0.652		
4	2	2	5	-31	0.206	0.851		
5	2	2	5	-4	0.072	0.673	0.702	0.084
1	2	2	6	8	0.046	0.695		
2	2	2	6	10	0.089	0.772		
3	2	2	6	4	0.051	0.703		
4	2	2	6	-27	0.173	1.024		
5	2	2	6	3	0.052	0.725	0.784	0.138

PRINCIPAL STUDY RESULTS

Bottle Number	Brand	Size	Time	nV Reading	µgF/Module (initial dry weight)	Cumulative Total	Sample Group Mean	Standard Deviation
1	2	2	7	13	0.038	0.733	0.844	0.177
2	2	2	7	9	0.061	0.833		
3	2	2	7	17	0.035	0.738		
4	2	2	7	19	0.127	1.151		
5	2	2	7	11	0.038	0.763		
1	3	-	1	143	NFLR			
2	3	-	1	143	NFLR			
3	3	-	1	144	NFLR			
4	3	-	1	144	NFLR			
5	3	-	1	145	NFLR			
1	3	-	2	134	NFLR			
2	3	-	2	141	NFLR			
3	3	-	2	143	NFLR			
4	3	-	2	146	NFLR			
5	3	-	2	145	NFLR			
1	3	-	3	133	NFLR			
2	3	-	3	137	NFLR			
3	3	-	3	141	NFLR			
4	3	-	3	145	NFLR			
5	3	-	3	147	NFLR			
1	3	-	4	133	NFLR			
2	3	-	4	140	NFLR			
3	3	-	4	143	NFLR			
4	3	-	4	145	NFLR			
5	3	-	4	146	NFLR			
1	3	-	5	155	NFLR			
2	3	-	5	153	NFLR			
3	3	-	5	152	NFLR			
4	3	-	5	152	NFLR			
5	3	-	5	151	NFLR			
1	3	-	6	158	NFLR			
2	3	-	6	154	NFLR			
3	3	-	6	156	NFLR			
4	3	-	6	153	NFLR			
5	3	-	6	151	NFLR			
1	3	-	7	127	NFLR			
2	3	-	7	134	NFLR			
3	3	-	7	139	NFLR			
4	3	-	7	142	NFLR			
5	3	-	7	145	NFLR			

APPENDIX 5

Analysis of Variance and Student - Newman - Keul test (multiple comparison) for principal study of fluoride release from elastomeric modules over seven designated time intervals.

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
BRAND	1	17.391654	17.391645	91.89	0.0001
SIZE	1	8.514605	8.514605	44.99	0.0001
BRAND*SIZE	1	29.319347	29.319347	154.91	0.0001
WP	16	3.028203	0.189263	20.99	0.0001
TIME	6	34.285019	5.714170	633.70	0.0001
BRAND*TIME	6	0.643952	0.107325	11.90	0.0001
SIZE*TIME	6	2.773230	0.462205	51.26	0.0001
BRAND*SIZE*TIME	6	6.424977	1.070830	118.76	0.0001
ERROR	96	0.86564	0.00902		
CORRECTED TOTAL	139	103.24662			
	R-Square	C.V.	Root MSE	CUM_TOT Mean	
	0.991616	5.706287	0.0950	1.6641	

TIME=1 (24 Hours)

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	2.3244293	0.7748098	223.85	0.0001
ERROR	16	0.0553804	0.0034613		
CORRECTED TOTAL	19	2.3798097			
	R-Square	C.V.	Root MSE	CUM_TOT Mean	
	0.976729	6.615980	0.0588	0.8893	

SNK Grouping	Mean	N	TYPE
A	1.25020	5	2
B	1.11960	5	1
C	0.82460	5	3
D	0.36260	5	4

TIME=2 (48 Hours)

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	4.3199598	1.4399866	106.55	0.0001
ERROR	16	0.2162268	0.0135142		
CORRECTED TOTAL	19	4.5361865			

R-Square	C.V.	Root MSE	CUM_TOT Mean
0.952333	9.821356	0.1163	1.1837

SNK Grouping	Mean	N	TYPE
A	1.71060	5	2
B	1.40800	5	1
C	1.16420	5	3
D	0.45180	5	4

TIME=3 (72 Hours)

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	5.7767317	1.9255772	108.98	0.0001
ERROR	16	0.2827100	0.0176694		
CORRECTED TOTAL	19	6.0594417			

R-Square	C.V.	Root MSE	CUM_TOT Mean
0.953344	9.768598	0.1329	1.3608

SNK Grouping	Mean	N	TYPE
A	1.96580	5	2
B	1.60060	5	1
C	1.37120	5	3
D	0.50540	5	4

TIME=4 (240 Hours)

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	9.0366388	3.0122129	100.33	0.0001
ERROR	16	0.4803624	0.0300226		
CORRECTED TOTAL	19	9.5170012			

R-Square	C.V.	Root MSE	CUM_TOT Mean
0.949526	10.06918	0.1733	1.7208

SNK Grouping	Mean	N	TYPE
A	2.4002	5	2
B	1.9492	5	1
C	1.9308	5	3
D	0.6030	5	4

TIME=5 (408 Hours)

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	12.506577	4.168859	87.48	0.0001
ERROR	16	0.762448	0.047653		
CORRECTED TOTAL	19	13.269025			

R-Square	C.V.	Root MSE	CUM_TOT Mean
0.942539	10.79923	0.2183	2.0214

SNK Grouping	Mean	N	TYPE
A	2.6614	5	2
A	2.6050	5	3
B	2.1176	5	1
C	0.7016	5	4

TIME=6 (576 Hours)

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	14.762759	4.920920	78.05	0.0001
ERROR	16	1.008728	0.063046		
CORRECTED TOTAL	19	15.771487			

R-Square	C.V.	Root MSE	CUM_TOT Mean
0.936041	11.48437	0.2511	2.1864

SNK Grouping	Mean	N	TYPE
A	2.9880	5	3
A	2.7716	5	2
B	2.2020	5	1
C	0.7838	5	4

TIME=7 (744 Hours)

Dependent Variable : CUM_TOT

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	16.340661	5.446887	80.10	0.0001
ERROR	16	1.087988	0.067999		
CORRECTED TOTAL	19	17.428649			

R-Square	C.V.	Root MSE	CUM_TOT Mean
0.937575	11.40462	0.2608	2.2865

SNK Grouping	Mean	N	TYPE
A	3.2274	5	3
B	2.8332	5	2
C	2.2418	5	1
D	0.8436	5	4

APPENDIX 6

Analysis of Variance and Student Newman Keul test (multiple comparison) for principal study of fluoride release from elastomeric modules in three designated time intervals.

TIME 3 - TIME 1 (0 - 72 Hours)

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	0.8667938	0.2889313	36.05	0.0001
ERROR	16	0.1282312	0.0080144		
CORRECTED TOTAL	19	0.9950250			
	R-Square	C.V.	Root MSE	CUM_TOT Mean	
	0.871128	18.98695	0.0895	0.4715	
	SNK Grouping	Mean	N	TYPE	
	A	0.71560	5	2	
	B	0.54660	5	3	
	B	0.48100	5	1	
	C	0.14280	5	4	

TIME 7 - TIME 3 (72 - 744 Hours)

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	6.4766282	2.1588761	68.03	0.0001
ERROR	16	0.5077836	0.0317365		
CORRECTED TOTAL	19	6.9844118			
	R-Square	C.V.	Root MSE	CUM_TOT Mean	
	0.927298	19.24357	0.1781	0.9258	
	SNK Grouping	Mean	N	TYPE	
	A	1.8562	5	3	
	B	0.8674	5	2	
	B	0.6412	5	1	
	C	0.3382	5	4	

TIME 7 - TIME 1 (0 - 744 Hours)

Source	DF	Type I SS	Mean Square	F Value	Pr > F
TYPE	3	9.8040022	3.2680007	62.82	0.0001
ERROR	16	0.8323936	0.0520246		
CORRECTED TOTAL	19	10.6363957			

R-Square	C.V.	Root MSE	CUM_TOT Mean
0.921741	16.32414	0.2281	1.3973

SNK Grouping	Mean	N	TYPE
A	2.4028	5	3
B	1.5830	5	2
C	1.1222	5	1
D	0.4810	5	4

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