



Review

Welding methods for joining thermoplastic polymers for the hermetic enclosure of medical devices

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ABSTRACT

New high performance polymers have been developed that challenge traditional encapsulation materials for permanent active medical implants. The gold standard for hermetic encapsulation for implants is a titanium enclosure which is sealed using laser welding. Polymers may be an alternative encapsulation material. Although many polymers are biocompatible, and permeability of polymers may be reduced to acceptable levels, the ability to create a hermetic joint with an extended life remains the barrier to widespread acceptance of polymers for this application. This article provides an overview of the current techniques used for direct bonding of polymers, with a focus on thermoplastics. Thermal bonding methods are feasible, but some take too long and/or require two stage processing. Some methods are not suitable because of excessive heat load which may be delivered to sensitive components within the capsule. Laser welding is presented as the method of choice; however the establishment of suitable laser process parameters will require significant research.

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1. Introduction

Implantable prosthetic devices in medicine require hermetic encapsulation to isolate internal components from the chemically aggressive *in vivo* environment. This is particularly important for active implanted devices, where functionality may be compromised by exposure to ingress of moisture or electrolytes. The

hermetic encapsulation of these devices is not only important for shielding the contents, but also for protecting the surrounding tissue from exposure to harmful extracts leached from the contents. Therefore the joining of materials to create the desired hermetic seal is vital. Polymeric substrates are currently not clinically used for encapsulating active implantable devices due to challenges associated with material permeability and hermetically sealing the capsule. The latter aspect is the focus of this review. Metallic encapsulating materials have been used successfully for long-term applications, for example, in cochlear and pacemaker implants. Metallic hermetic encapsulation has been discussed extensively in

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the literature for applications in electronics and automotive industries [1–4]. Titanium and its alloys have been remarkably successful in meeting the fundamental criteria for implant packaging, which include biocompatibility, low permeability of the substrate material to ions and water vapour, structural and dimensional stability, and a hermetic seal readily achieved by laser welding [2,3]. The success of titanium has somewhat slowed the development of alternative materials, for example polymers, and design approaches. Ceramics have also been used for active implant packaging, particularly for implantable electronics where a metal case interferes with the transmission of electrical signals in and out of the device [5,6]. A receiving coil can be hermetically encased within the same ceramic enclosure as the electronic circuitry [7]. This can significantly reduce the implant volume, and hence the risk of foreign body reaction [8]. The major drawback in using ceramic packaging materials for medical implants is their inherent brittleness, which makes them more vulnerable to impact related failures [8,9]. Moreover, high stress concentrations at edges can lead to cracks, and hence catastrophic failure.

The applications for hermetic encapsulation technologies are broadening, which include cochlear devices, ventricular assist devices, and the artificial eye; and interest in alternative packaging materials is growing [10,11]. There has been long-term interest in the use of polymers as substrate materials for hermetic encapsulation, however polymeric materials have not yet been demonstrated as a viable alternative to titanium or ceramic encapsulation owing to uncertainties associated with the permeability of the material and the hermeticity of joints required to form the enclosure. In other industries however, thermoplastic polymers are increasingly replacing metallic components due to the advantages of light-weight materials and cost-efficient manufacturing processes [12]. If a polymer can prove to be joined hermetically and be impervious to water vapour at levels acceptable for long-term implant applications, the medical device industry would be revolutionised with regard to volume output and implant design opportunities.

Many polymers are permeable to gases, including water vapour, and the polymeric encapsulation of active implantable devices for long-term applications is a challenging task. The advent of new polymer materials, such as high performance engineering thermoplastics which have inherently reduced permeability, now increases the viability of the use of polymers for encapsulation. Improved barrier properties of polymers can be achieved by adding inorganic multi-layers [13] or nanocomposites which contain dispersed inorganic nanoplatelets [14]. The addition of nanoplatelets increases tortuosity, therefore increasing the diffusion path of a permeating gas molecule. Such progress in the improvement of the barrier properties of polymers has greatly increased their potential for use in the implantable medical device industry. Establishing appropriate joining techniques for polymeric encapsulation, which demonstrate hermeticity over an implant lifetime in an *in vivo* environment, is the next design goal, which is the focus of this review.

This article addresses the potential use of polymers as packaging materials for active implants and joining techniques for achieving a hermetic seal. The concept of the polymeric enclosure for active implants that this review addresses is shown in Fig. 1. The key reasons for the significant shift from metals to polymers in industry are discussed in the next section. For implant applications, thermoplastics are identified as the most promising class of polymer. This is then followed by an overview of the established joining techniques for thermoplastics, highlighting the advantages and disadvantages for implantable applications. Examples of where some of the joining techniques have been applied to assess polymer based packages for potential medical applications are then described.

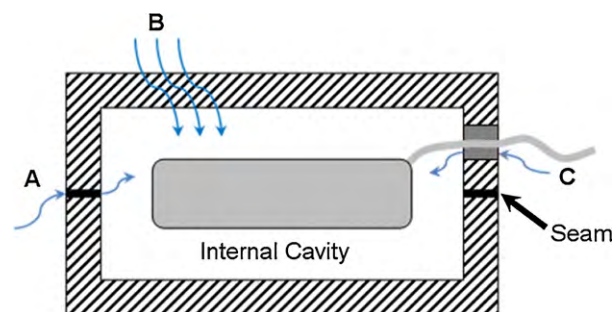


Fig. 1. Schematic of a generic hermetic enclosure for an active implantable device, showing areas where hermeticity may be compromised when the enclosure substrate is a polymeric material (blue arrows). (A) Ingress may occur via the seam. The enclosure is fabricated from two parts which are joined. This seal must be sufficiently hermetic so potential ingress path is avoided. (B) Permeability through the packaging substrate. (C) The feedthrough also requires hermetic sealing to ensure ingress does not occur via this path. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

2. Advantages of polymers

Thermoplastic polymers have progressively been replacing metals in the automotive and aerospace industries over the past few decades. This has resulted in significant cost efficiency increases for these industries. A reduction in the cost of manufacturing is not the only factor: weight saving, flexibility and thermal insulation properties are also important. New design opportunities are also introduced by polymers. The use of polymers as replacements for metals in the automotive industry has been given additional impetus from the introduction of strict emission laws, for example, the *European Emissions Standards* for new vehicles sold in EU member states [15,16]. Two decades ago 6% of the average family car was comprised of plastic; this has risen to 15% today [15]. In the aerospace industry, aircraft fuel efficiency is also a major driver of polymer substitution for metal, and the associated research and development. For other consumer products, such as computers and mobile phones, the adoption of polymers has provided advantages which also include electrical insulation and electromagnetic signal transmission.

The use of polymeric materials in the medical industry was revolutionised by the rapid developments in polymer science in the early half of the 20th century, particularly developments at the beginning of World War II. The end of World War II resulted in a so-called polymer revolution [17], when polymers that were restricted for military use became available for peacetime use [18]. Shortages in metals such as steel during the war required scientists to consider alternative synthetic materials. Polymers such as nylon and polytetrafluoroethylene (PTFE) became widely used; nylon was used to make such items as ropes, tents, and parachutes, and PTFE was used to coat metallic components due to its superior resistance to corrosion. As for biomedical applications, polymethylmethacrylate (PMMA) was one of the first polymers investigated as an implantable biomaterial [18]. PMMA has since been extensively used for a number of applications, such as bone cement, prosthetic joint replacement, bone fillers and dental applications [19].

Cheap, disposable polymeric medical devices are now common place due to the manufacturing flexibility of plastics. Examples include the replacement of glass syringes with disposable plastic syringes, and flexible blood storage bags made of poly(vinyl chloride) (PVC). Biodegradable polymers such as polylactic acid and polyglycolic acid are used extensively as synthetic biodegradable sutures, stents and drug delivery devices [20,21]. For orthopaedic applications, effort has been directed to the use of polymers which have elastic modulus values closer to that of bone than the standard metals used [21–23].

The advantages discussed above also transfer to some degree to the use of polymers for encapsulating implantable medical devices. Additionally, biomedical polymers do not interfere with medical imaging technologies, such as MRI and CT [24]. Metal related artefacts are problematic in post-operative patient management where star-burst artefacts or streaking can considerably degrade image quality [25–28].

Polymers used in the medical industry can be classed as thermoplastics, thermosets or elastomers. Thermoplastics are the most commonly used, because they are able to be reheated, remoulded, have good thermal and chemical stability, and can readily be recycled. They also have good fatigue resistance and high fracture toughness [12]. Upon heating above the glass transition temperature (T_g), thermoplastics will soften, and eventually liquefy. Upon cooling, solidification occurs and the process can be repeated, with little to no effect on the properties of the material. Examples of thermoplastic polymers are polypropylene (PP), polyethylene (PE), polyetheretherketone (PEEK), and PMMA. Thermosetting polymers, however, cannot be reheated and remoulded. When formed, thermosetting polymers become permanently hard and do not soften at elevated temperatures; instead they begin to degrade [29]. This property makes thermosets unsuitable for injection moulding. Examples of thermosetting polymers are vulcanised rubber and epoxies. Elastomers, due to their unique elastic properties, are limited to applications where large deformations are required. Polyurethane is a commonly used medical elastomer and applications include artificial heart valves [30,31] and wound dressing films [32]. Thermoplastics are generally selected as a packaging material where structural integrity and protection of contents is required. Thermoplastics can be injection moulded into complex shapes and small dimensions. Furthermore, injection moulding with thermoplastics can lead to high volume production, increased output, and reduced costs, in comparison with production using metals.

Polymers, and particularly thermoplastics, have demonstrated their versatility and applicability in replacing metals for a range of applications. In the medical device industry, for applications where lifetime *in vivo* hermeticity is not essential, polymers are often the material of choice. However, for devices that require long-term hermeticity, metals are still considered the gold standard. For polymeric packaging, the joining method and the assurance of a hermetic seal remain a significant challenge. Replacement of metals with polymers as implantable packaging materials calls for guaranteed long term polymer bonding technologies. Joining and sealing polymer parts for long-term implantation still needs to be established and proved for implementation of this approach. The next section details the current joining methods available for thermoplastics which would be most suited to long-term *in vivo* applications.

3. How to join thermoplastics

Techniques used for joining thermoplastics fall under three categories: mechanical fastening, adhesive bonding, and direct bonding. Not all of these are suitable for implantable devices. Mechanical fastening including clipping, clamping, screwing, or riveting can be used in medical implants, but not when the enclosure is required to be hermetic. The quality of the seal can be improved by the use of an O-ring; however the complexity of the connection and possibility of introducing some trapped volume are disadvantages. Adhesive bonding of thermoplastics can be successful with some polymers for non-implantable applications, but is not suitable for implants where longevity is required [33]. Adhesives tend to degrade over time in an aqueous environment, compromising the strength and integrity of the seal [34]. Adhesive bonding

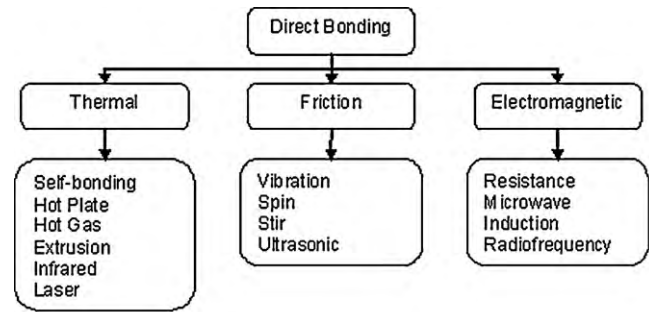


Fig. 2. Direct bonding techniques and classifications for thermoplastic polymers.

also introduces a third material (the adhesive) which potentially releases harmful by-products. For example, cyanoacrylate derivatives have successfully been used for many years for superficial skin closure; however *in vivo* use may cause unwanted side effects, such as inflammation and tissue necrosis [35,36]. *In vivo* degradation of medical adhesives is not clearly understood, and degradation by-products such as formaldehyde have been shown to be potentially toxic to cells [37]. Solvent assisted bonding is a technique that is emerging as a popular bonding technique for thermoplastics in the fabrication of microfluidic devices, and particularly those made of PMMA [38]. However, many high performance polymers are resistant to solvents, and require the use of specialised solvents if they are available. The potential for toxic by-products of solvents suggests that the bonded enclosure may not meet the biocompatibility requirements needed for long-term *in vivo* applications.

We define direct bonding as the permanent joining of two materials without the use of adhesive or other chemical product at the interface. Direct bonding is also referred to as welding, fusion bonding, “glueless” bonding, or autoadhesion. Direct bonding can be applied to many thermoplastic materials, and is a long established method used in the automotive, aircraft, packaging, and medical industries [39]. Direct bonding methods typically involve the application of localised heat and pressure. The overall aim of a direct bond between thermoplastics is the creation of a seamless joint that ideally possesses the same strength as that of the bulk material. This concept is particularly suitable for active implantable medical devices, where a hermetic seal is required to enclose and protect electronic components. There are a number of techniques available for direct bonding or welding of thermoplastics, and these are often classified in terms of the method of heat generation at the joint interface (see Fig. 2). There are three main methods of heat generation: thermal, friction and electromagnetic. The reader is directed to a number of review articles that comprehensively detail these techniques and their applications [12,40–44].

3.1. Thermal bonding

In thermal bonding the polymer surfaces to be joined are heated and pressure is applied until the bond is formed. In the first thermal technique listed in Fig. 2, self-bonding, a bond is formed between two surfaces without reaching the melting point. The entire sample is heated and pressure is applied to the interface between the parts to promote chain interdiffusion. The resulting bond strength with this method can be greater than other direct bonding techniques [45,46]. However, it is not practical if the internal components of the implant are heat sensitive and the temperature required exceeds their tolerance temperature.

The other thermal techniques listed in Fig. 2 involve application of localised heat, and this is more suitable for an implanted active device as it only heats the areas to be joined. The listed processes involve melting the joint surfaces, followed by application

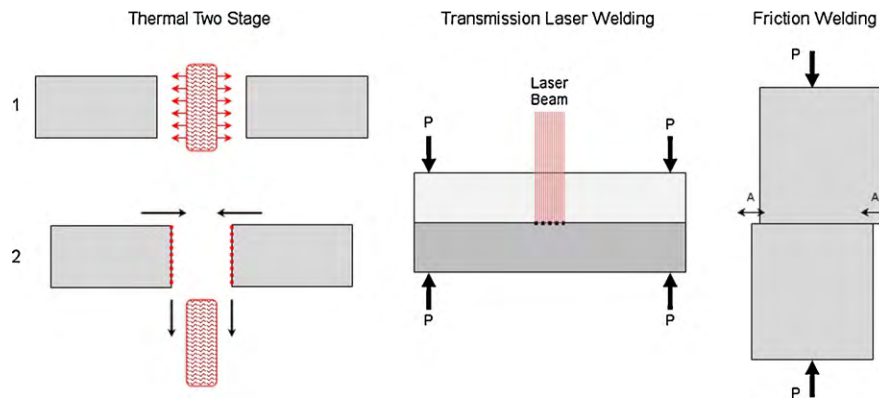


Fig. 3. Schematics of three common thermoplastic welding techniques: thermal two stage, transmission laser welding, and friction welding. Hot-plate and infrared welding are examples of thermal two stage techniques. A heat source is introduced between the joining surfaces until the surfaces melt, the heat source is then removed and the surfaces are brought into contact under pressure until the joint solidifies. In hot-plate welding the heat source makes contact with the joint surfaces while no contact occurs in infrared welding. In transmission laser welding a beam passes through a laser transparent top layer and is absorbed at the interface by laser absorbing material either within the bottom layer or applied at the interface. In friction welding the bottom substrate is stationary while the top substrate is moved parallel to the surface at amplitude A. Pressure (P) is used to maintain intimate contact during welding and cooling processes.

of pressure until the polymer cools and the joint consolidates (see Fig. 3).

In hot-plate welding, a heated plate is pressed onto the surfaces that are to be welded causing localised melting. Shim and Kim [47] used hot-plate welding to bond acrylonitrile butadiene styrene (ABS) polymer using a lap-joint configuration. They found that the strength of the bond increased with plate contact time and temperature, and sufficient flow of the molten polymer was the main factor for development of joint strength. Hot-plate temperatures of 180 °C, 200 °C, 220 °C, 240 °C and 260 °C were compared with contact times of 10, 20, 30, 40, 50 and 60 min. For each contact time, the maximum bond strength was achieved at 260 °C, increasing from approximately 8 MPa to 11 MPa for each time step. A drawback they noted was that severe deformation occurred with higher temperatures. The lap-joint samples failed in both shear (within the bond) and tension (within the substrate; which is the most desired outcome). Substrate failure was attributed to notches and defects in the polymer. Plastic deformation of the substrate was evident in the failure zone of the weld, indicating a relatively strong bond. Watson and Murch welded PP, polystyrene (PS), and poly(phenylene oxide) circular tubing and also found that the most significant parameters for obtaining good welds were those associated with the heating phase (hot-plate time and temperature) [48]. Weld strengths equal to the parent material were able to be attained, but were dependent on the process parameters selected. Nonhof conducted experiments on ABS and PP to determine optimal welding parameters for hot-plate welding used in mass production [49]. This author emphasised the difficulty in determining a single optimal parameter setting for hot-plate welding, due to the vast plastic types and applications available. Nonhof proposed that a full factorial experimental design is the best method for determining the optimal parameters for hot-plate welding. Nieh et al. assessed the crystallisation kinetics of PP during hot-plate welding; a model to predict crystallisation was developed with good correlation to experimental results [50,51]. A disadvantage of the hot-plate welding technique is melt residue adhering to the hot-plate surface, particularly for high melting temperature thermoplastics [52,53].

Hot-gas welding uses a stream of hot gas to melt a filler rod positioned between two adjoining surfaces. Extrusion welding also uses a stream of hot gas, but instead of a filler rod, molten polymer is injected into the joint [39]. The bond quality of hot-gas welds is dependent on welding speed, pressure, and gas temperature [44]. Balkan et al. compared hot-gas butt welding of PE, PP and PVC [54]. The overall tensile strength of the PVC to PVC bond was found to be lower than the equivalent PE–PE and PP–PP bonds. PVC bonds var-

ied in the range 45–77% of the parent material strength compared to 77–90% and 63–80% for PE and PP, respectively. The weaker PVC bond strength was attributed to the greater degree of amorphous characteristic of the PVC, where PE and PP had higher crystalline content. None of the bonds in this study reached the strength of the parent material, and all bonds failed within the weld line. Consistent with Balkan et al., Marcziš et al. compared bond strengths of a number of thermoplastics, and found the amorphous polymers gave lower bond strengths, due to a slow melt flow that led to chemical decomposition followed by quick degradation [55]. Extrusion and hot-gas welding are, however, manual techniques which require a skilled operator, making these methods unsuitable for high volume and high tolerance manufacturing.

Infrared welding melts the bond surfaces using infrared radiation; the process is similar to hot-plate welding, but an advantage of this method is that the heat source does not contact the polymer, and it is therefore better suited to high melting temperature thermoplastics. The infrared energy is typically delivered via electrically heated metal plates or infrared lamps [44]. As with the methods already discussed, the heating time and pressure are important process parameters. Additional process parameters which affect the quality of the bond are the distance between the heat source and surfaces to be bonded, and the change-over time, which is the time between removal of heat source and contact of the parts. Studies assessing infrared welding of thermoplastics have shown that joint strength increases with molten-layer thickness, until an optimum is reached and then decreases with further increases in molten-layer thickness [44,56,57]. The main disadvantage with this method is that polymers have different absorption characteristics and in most cases this technique will also require pigmentation (e.g. carbon black) for adequate melting to occur [58]. Another disadvantage is the cooling of the melt layer during the change over phase, which can decrease the joint strength [44]. In order to avoid cooling, longer heating times are necessary, but this increases the cycle time and potential of thermal decomposition of the surface layer.

In laser welding, a laser beam is used to melt the polymer at the joint interface. Both butt joint and lap-joint configurations can be welded. In transmission laser welding (TLW), applicable to lap-joints, the laser passes through a laser transparent, non-absorbing layer, and into an absorbing bottom layer, where the absorption occurs at the interface. The absorption of energy causes melting of the polymer at the bond interface (see Fig. 3). The key parameters that influence the bond quality are laser power, scan speed, laser beam uniformity, absorption properties of the material at the interface, and the clamping pressure [59]. Laser welding is a

high speed process, creating joins almost instantaneously, and it achieves repeatable and high strength bonds. Furthermore, the heat affected zone (HAZ) within the weld is smaller with laser welding than other techniques [44]. The HAZ in polymer welding is the area immediately adjacent to the joint which is affected by heat as a result of thermal conduction. The HAZ is not exclusive to laser welding, but to all welding techniques where heat is generated [60,61]. Potente et al. investigated joining PEEK to PEEK utilising quasi-simultaneous TLW [62]. T-joints were fabricated and the bottom layer of PEEK was pigmented with various concentrations of carbon black. Scanning speeds ranging from 0.1 to 10 m/s were assessed against laser power densities ranging from 3 to 13 W/cm². They found that weld strength increased with increasing laser power and slower welding speed, finding a 33% increase in strength when comparing a combination of 3 W/cm² and 10 m/s with 13 W/cm² with 0.1 m/s. At the optimum parameter conditions, joint failure was not at the bond interface but within the bulk material in some cases. Acherjee et al. investigated transmission laser welding to join PMMA (lap-joint) and the effects of changing process parameters on weld strength and weld-seam width [63]. Carbon black (0.2 wt%) was used as the absorbing pigment in the bottom layer of PMMA. Maximum weld strengths in the order of 50 MPa were achieved. Increases in laser power were shown to increase strength and weld width, while increases in speed decreased both these parameters. For example, a strength of 35 MPa resulted for a laser power of 19 W and speed of 420 mm/min, compared to 53 MPa for 25 W and 300 mm/min. Georgiev et al. assessed the interfacial bond formation of welding Teflon FEP (fluorinated ethylene propylene) to titanium foil using transmission laser welding [64]. Ti–F bonds were formed within the interfacial region only, with no chemical bond formation within the surrounding HAZ.

The process of laser butt welding is similar to that of hot-plate and infrared welding, but a laser beam is used to heat and melt both joint surfaces prior to contact. This requires both polymer surfaces to be laser absorbent. This technique is suitable for highly heat-resistant thermoplastics, where melt residue may stick to the hot-plate surface [52,53]. Laser butt welds have been investigated using PE and PP, where joint strengths matching the parent material strength were achieved [53]. In order to laser weld two polymers that are both laser transparent, infrared absorbing pigments are often added to the bulk of the absorbing layer. There are several commercial products available for absorbing energy in the interfacial region (such as Irodin[®], Lumogen[®]). Some of the laser absorbing pigments may affect the colour of the polymer to which they are added. Under certain circumstances, where appearance is of high importance, this may be a drawback to the use of these types of dyes and the TLW bonding technique. For welding two laser transparent polymers (without the need of adding pigments), the Clearweld technique can be used [59]. Clearweld is an infrared absorbing dye which is virtually colourless. Clearweld joints were shown to have lower residual stresses than conventional TLW (16% lower), ultrasonic (35% lower), and vibration welds (35% lower) in a study which compared the residual stresses in polycarbonate (PC) for various welding techniques [65,66]. Hot-plate welding was the only method with lower residual stresses than Clearweld and the other methods; however hot-plate welding is a much slower process than laser welding [66].

The thermal bonding techniques discussed so far include a crucial forging step, where pressure is applied until the joint cools and consolidation occurs. The role of pressure in producing a strong bond should not be underestimated. The importance of applying pressure is related to delivering intimate contact between the two contacting surfaces. If full intimate contact is not achieved and small gaps are present, then these gaps may not bridge during heating [67,68]. These unfused areas can act as notches and hence compromise the mechanical integrity of the bond. Additionally,

both Potente et al. and Balkan et al. have highlighted the importance of applying pressure for transporting thermally damaged material out of the joining zone, and homogenising the material at the interface, and thus increasing the achievable weld strength [54,62]. However, increasing the pressure too much can cause a decrease in the molten-layer thickness and thus reduce the bond strength [44,62,67,68].

3.2. Friction welding

Friction welding uses the heat generated by rubbing two surfaces together to melt and bond mating parts (see Fig. 3). As with thermal bonding techniques, the two parts are then held together under pressure until the bond cools and consolidates. The most common friction welding techniques are vibration, spin, stir and ultrasonic welding.

In vibration welding, one part is fixed, while the other is vibrated parallel to the bond line at a specific frequency and amplitude. Vibration is continued until the mating surfaces melt; the parts are then aligned and pressed together until consolidation. This technique is generally limited to parts with flat mating surfaces, and is mostly used to bond relatively large parts, such as intake manifolds and bumper assemblies for cars [42,44]. During the initial phase of welding, when a high friction coefficient exists, high bending forces can result. This technique requires specialised fixtures, and the thermoplastic to be bonded must be stiff enough to avoid deformation during the welding process. Early studies assessing the process parameters for vibration welding have shown that the most significant parameter affecting bond strength is the weld penetration distance, which is the decrease in the dimension of the part at right angles to the weld as a result of lateral outflow of the molten plastic [69–72]. These studies have also indicated that there is a threshold penetration distance, below which the bond strength falls [73–75]. Stokes demonstrated that bonding PC, poly(butylene terephthalate) (PBT), and poly(ether imide) (PEI) to themselves, resulted in weld strengths equal to that of the bulk material [69–71]. For ABS however, the highest achievable weld strength was found to be lower than the bulk material (90–95% of the bulk material) [75]. Notably, failure of ABS welds was also due to a different mechanism than for the other polymers. PC, PBT and PEI all failed at the weld site as a result of plastic flow under load, whereas ABS failures primarily resulted from crazing (fine cracking) and crack propagation within the weld area [75]. In another study, Cakmak et al. investigated the bond development of amorphous and semi-crystalline poly(ethylene naphthalate) (PEN) during vibration welding [76]. A marked difference in failure strength between amorphous and crystalline PEN was seen, where the crystalline PEN welds were twice as strong as the amorphous PEN welds. This was also evident in the failure locations; the amorphous welds all failed at the weld midline, through the HAZ, while the crystalline failures were not always within the HAZ. The proposed mechanism of bond failure for amorphous PEN was preferential alignment of the naphthalene planes parallel to the direction of the weld interface, with weak interchain forces between the planes, so that failures occurred between these planes. For the crystalline PEN, the degree of oriented naphthalene planes within the weld line was much lower, with a consequent increase in strength. The microstructure of the HAZ in vibration welded polyamide (PA) butt joints was assessed by Chung and Kamal [60]. The weld zone was shown to consist of two distinct regions of HAZ: a central layer which was recrystallised from the molten polymer, and a deformed outer layer which was the result of polymer deformation above T_g . The central layer had higher molecular orientation than the outer layer, and in tensile tests failure occurred through the interface between the inner and outer HAZ layers. Moreover, the results suggested that the determining factor for weld strength was the crystallinity of the central HAZ layer,

where increases in crystallinity correlated with increases in weld strength.

Ultrasonic welding is vibration welding at an ultrasonic frequency (20–40 kHz). Ultrasonic vibrations are transmitted through the material, and melting begins at irregularities at the contact surfaces called 'energy directors'. This technique is the most commonly used welding method for thermoplastics [44]. It is also commonly used in the medical industry for manufacturing non-implantable medical devices, where hermetic seals and contamination-free joints are required. A drawback with ultrasonic vibration is that it requires energy directors to be incorporated at the seam, which can restrict design and manufacturing processes. Additionally, the technique has limited applicability to semi-crystalline polymers. Two approaches are available for ultrasonic welding of thermoplastics; near-field (interface less than 6 mm from the ultrasonic horn) or far-field (interface greater than 6 mm from the horn) [77–79]. All thermoplastics can be welded in the near-field configuration with the correct choice of parameters. In the far field configuration, the ability of the polymer to transmit, rather than dampen, ultrasonic waves must be taken into account. Semi-crystalline polymers such as HDPE, PP, PE, and polyester are generally difficult to weld ultrasonically due to the greater energy required to melt crystals and initiate intermolecular diffusion, and they are particularly difficult in the far-field configuration, due to damping. Liu et al. ultrasonically welded amorphous polystyrene (PS) and semi-crystalline PP [80]. They found that weld time and amplitude of vibration were significant parameters affecting weld strength. The semi-crystalline PP weld strength was three times higher than the amorphous PS weld strength (26 MPa versus 8 MPa, respectively), and required more energy to achieve optimum bond strength than the amorphous PS. The shape of the energy director is also a significant parameter and studies have been conducted to assess the effect of shape differences on bond quality [79,81,82]. Chuah et al. assessed three energy director shapes in far-field ultrasonic welding of amorphous ABS and semi-crystalline polyester [81]. The resulting weld efficiency, calculated as weld strength divided by parent material strength, was found to be significantly affected by the shape of the energy director. A semi-circular shape was found to result in higher weld efficiency than a rectangular or triangular shape; increases of up to 10% in weld efficiency were reported depending on the process parameter (weld time, weld pressure or hold time).

In spin welding, friction is generated by pressing and spinning the moving part against the fixed part. The influence of process parameters on the weld quality of various thermoplastics has been assessed by Tappe and Potente [83]. PA, PS, ABS, and high and low density PE cylinders were spin welded, and the influence of spin speed, axial pressure, friction time, and braking time was assessed. Parameters influencing weld strength were polymer dependent. Low weld strengths were attained for PA and PS (20% and 45% of the bulk material strength, respectively). High and low density PE achieved the highest weld strengths (80–100% of the bulk material, respectively), which was dependent on the spin speed. The highest weld strength achieved for ABS was 70% of the bulk material, and was influenced by spin speed and axial pressure. Spin welding can achieve strong and hermetic seals (for industrial pipe applications); however its application is limited to parts with circular and symmetric cross-sections.

Stir welding uses a head-pin of a metallic rotating tool to stir and mix the polymer at the joint line of two parts. Stir welding results in an exit hole when the tool is removed. Although this hole can be filled, it has the potential to act as a point of stress concentration and it may also reduce the hermeticity of the weld.

A major disadvantage of friction welding techniques for the encapsulation of active medical implants is the vibration imposed on the contents of the package. Another drawback is the generation

of fine particulates. This poses a problem for sealing microfluidic reservoirs and for implantable packages where microscopic particulates could have adverse effects on internal components.

3.3. Electromagnetic welding

The main types of electromagnetic welding are resistance, microwave, induction and radiofrequency welding.

In resistance welding (or resistive implant welding), an electrically resistant material is implanted between the two parts to be joined. A current is then passed through the implanted material, which heats up and melts the surrounding polymer. Resistance welding was developed for the welding of thermoplastic matrix composites (e.g. those that contain carbon fibres), and in the literature, optimal process parameters giving maximum bond strength are determined for thermoplastic composites [84–90]. Although the embedded material can be any electrically conductive material [91], carbon fibres and stainless steel mesh are commonly used [24]. Resistance welding for thermoplastics is a reliable method, with reported lap-shear strengths equal or close to the parent material strength [87]. The most commonly resistance welded thermoplastic composites are carbon fibre (CF) reinforced PEEK, glass fibre (GF) and CF reinforced PEI, and GF and CF reinforced PP [84,90].

In microwave welding, a layer of electromagnetic absorbent material is placed between the parts to be joined. The material is heated using microwave power which heats and melts the surrounding polymer. Materials containing polar groups in their molecular structure are able to absorb microwave energy, with the most common implant material being polyaniline (PANI). Some thermoplastics such as ABS, PVC, and nylon contain polar groups in their molecular structure, and are able to be welded without an additional absorbing layer. Few studies have been performed on microwave welding of thermoplastics since it is a relatively new polymer welding technique. Wu and Benatar developed a microwave joining method (butt joint) for HDPE using PANI at the weld line [92]. They found that the thickness of the molten layer influenced strength, with greater thicknesses resulting in stronger bonds. At the optimal welding conditions, the tensile strength of the weld was equal to that of the HDPE bulk strength (25 MPa). Staicovici et al. looked at the welding and disassembly of HDPE butt joints with various PANI concentrations at the weld line [93]. They found that the tensile strength of the joints could reach that of the bulk material strength of HDPE under the right conditions. However, the PANI concentration that resulted in effective disassembly displayed a maximum joint strength of only 80% of the bulk material, i.e. PANI concentrations that achieved joint strengths equal to the bulk material did not disassemble effectively.

Radiofrequency welding (or high frequency welding) uses an intense electromagnetic field to heat the polymer at the bond interface. Electrodes pressed onto either side of the parts to be joined apply the electromagnetic field. Only polymers with polar groups in their molecular structure can be welded using this technique. The weld quality is dependent on the dielectric loss factor of the polymer; polymers with a high factor will produce more heat [12]. Similar to microwave welding, PANI can be used within the joint interface for non-polar polymers such as HDPE [44]. The main applications for this technique are limited to thin sheets and films, and it is commonly used in the medical industry for packaging and sealing applications, such as blood bags. RF welding is not used for welding high temperature thermoplastics; it is commonly used to weld softer polymers, such as thermoplastic polyurethane (PU) elastomers [44]. The most commonly welded thermoplastics using this technique are polyesters, PA, PU, and PVC [39,41].

In induction welding, the plastic is implanted with conductive material which absorbs electromagnetic energy that is applied using an induction coil. The heat induced in the implant melts the

Table 1
Advantages and disadvantages of direct bonding techniques for thermoplastic polymers with respect to medical device applications.

Welding method	Advantages	Disadvantages
<i>Thermal</i> Self-bonding Hot-plate	High joint strengths can be achieved. Simple and economical.	Entire sample is heated, including internal components. Two-step process, contact of heating element, long process time, overheating and degradation can occur, not suitable for high T_m polymers.
Hot gas Extrusion Infrared	Economical, complex geometries. Shorter process time than hot gas. Non-contact heating, short process time, suitable for high T_m polymers.	Manual process—operator skill required. Manual process—operator skill required. Two-step process, highly dependent on polymer's absorption characteristics.
Laser	One-step process, highly localised heating, instantaneous bonding, no vibration, contact or particulates, low residual stresses. Broad range of laser absorbers available and corresponding wavelengths. Typical laser wavelength range for polymer welding is 800–1100 nm.	Requires laser absorption at interface, requires top part to be laser transmissive, part thickness limitations, may require pigmentation, high capital costs.
<i>Friction</i> Vibration	Short process time.	General: Particulate generation, vibrations imposed on the material and contents. Limited to larger components, restricted to flat surfaces, not for tight tolerance requirements, not for thin wall parts, high internal bending forces.
Spin	Simple and economical.	Components must have symmetrical and circular cross-section.
Stir	Economical.	Exit hole created; can act as stress-raiser, difficult to create even polymer mixing.
Ultrasonic	Economical, mass production, short process time.	Requires energy directors to be incorporated at seams. Limitations associated with semi-crystalline polymers.
<i>Electromagnetic</i> Resistance Microwave Induction Radiofrequency	General: Additional conductive or magnetic material at joint allows disassembly for recycling or re-use. Complex geometries. Short process time, complex geometries. Short process time, complex geometries. Short process time, simple and economical.	General (except radiofrequency): Requires conductive or magnetic material to be implanted at joint site, extra fabrication step, implanted material remains in joint. Unknown effects of electromagnetic field on internal components. Slow process time. Material degradation risk for polymers with polar groups. Expensive machinery. Insert at joint may corrode. Requires polymers with polar groups and high dielectric loss factor, limited to thin sheets/films.

surrounding polymer. This method is particularly suited to thermoplastics with carbon-fibre reinforcement due to the presence of electrically conductive carbon fibres, and therefore it requires no additional material at the joint interface [94,95]. Most thermoplastics can be welded using this technique and strong welds can be achieved [41].

The key drawback of electromagnetic welding for implantable device applications is the effect of the intense electromagnetic fields on sensitive metallic and electronic components within the enclosure. Furthermore, if an additional material is used within the joint interface it may affect the mechanical properties of the joint, and may also corrode which can decrease joint strength.

3.4. Summary

Table 1 summarises the main advantages and disadvantages for each of the methods discussed for applications to implantable medical device encapsulation. Laser welding, where it can be used, is the most suitable technique. It provides almost instantaneous bonding, highly localised heating, and minimal effect on sensitive contents. Ultrasonic or resistance welding could be considered in cases where laser welding is not possible.

A common trend highlighted in the above discussion is that amorphous polymers result in weaker bonds, compared to the bulk strength of the parent material. Semi-crystalline polymers generally require greater energy input in order for bonding to occur, but the resulting bond strength can match that of the bulk polymer. Joint strength is a standard parameter that is reported to indicate bond quality, however it should be noted that the strength can vary with joint configuration. Lap-joint configurations and butt-joint configurations can differ in measured strength, for the same welding parameters. This is due to the differing loading mecha-

nisms; in the lap-joint configuration, the joint is loaded in shear, in the butt-joint configuration, the joint is loaded in tension [96]. Moreover, the presentation of strength data should be interpreted with caution. Joint strength values are also dependent on the polymer that is being welded—differences in bulk material strength will dictate the maximum achievable strength that can be attained. Therefore, the most relevant value is bond efficiency, which is commonly reported. This presents the strength as a fraction of joint strength over the bulk material strength. The ideal situation is that in which the joint strength is equal to that of the bulk material strength; for the joint to fail, loads applied would have to exceed those that the polymer could inherently withstand, and this is a situation that designers aim to avoid.

4. Application of welding methods for polymer based encapsulation

The potential for implantable polymeric packaging within the medical device industry is beginning to be realised, and this is expected to generate a wave of new research. The choice of polymer and sealing technique depend on the application. The bond strength is a major indicator of joint quality. Hermeticity of the seal then needs to be sufficient for the duration of the intended implant period, and this longevity requirement needs to be demonstrated. Studies that assess effective polymer joining for encapsulation of implantable devices according to the concept shown in Fig. 1 are scarce. There is extensive research, however, within the implantable micro-device sector where polymers have become an attractive enclosure alternative, and a number of welding techniques described in the previous section have been assessed.

The literature on applications of polymeric packaging for microfluidics and microelectromechanical systems (MEMS) is a source of information on the performance of near hermetic devices. Joining approaches for sealing micro-packages have included adhesive bonding, but direct bonding techniques are preferred due to the protrusion of adhesive at the joint which can cause problems associated with flow alteration [97,98]. Thermal self-bonding has been assessed, but a major drawback is channel deformation and collapse associated with the bulk heating [98]. A number of the localised joining methods discussed in the previous section have also been assessed for microsystems, and the reader is directed to the comprehensive reviews by Tsao et al. and Becker et al. [97–99]. Additionally, implantable applications of microsystems are increasing [100,101], and much research into suitable enclosure materials has focussed on biocompatible polymers [97,99,101,102].

A number of studies by a group that assess transmission laser welding of thermoplastic polyimide to titanium coated glass for the purpose of microscale hermetic encapsulation are the only studies that investigate the key issues associated with polymeric enclosures, which include hermeticity and *in vivo* strength longevity [103–109]. Even though these studies do not assess complete polymer to polymer joining, they present important steps toward achieving this goal. The results indicated that laser welding is a suitable welding technique for creation of microjoints for microscale polymer enclosures. The group compared diode and fibre lasers and found that the fibre laser resulted in a 19% stronger bond than the diode laser [106]. Laser scan speed was also shown to affect the final bond strength, with slower speeds resulting in stronger bonds. An increase of 38% in bond strength was found when the laser scan speed was reduced from 1300 mm/min to 100 mm/min [107]. Soak tests in physiological solution for up to 12 weeks resulted in a reduction of bond strength by 50%, but the strength of the bond stabilised after 4 weeks [103,109]. It was hypothesised that the joint degradation was caused by water penetration through polyimide to the interface with the titanium. Enclosures with an internal volume of $1.5 \times 10^{-4} \text{ cm}^3$ were welded to assess joint hermeticity using a helium bomb test in order to detect leaks above $1 \times 10^{-9} \text{ std. cm}^3/\text{s}$ [110]. The helium leak rate was found to be $1 \times 10^{-7} \text{ std. cm}^3/\text{s}$, and it was concluded that the polyimide-titanium seal was near-hermetic. Post-implantation assessment after implant in a rat brain for 10 days showed that hermeticity was maintained, however, a 28% reduction in bond strength was observed [111]. The group concluded that the seals could be effective for short-term implants and that further optimisation was required for long-term implantation.

Laser welding has also been assessed for fabrication of microfluidic channels made of polyethylene terephthalate glycol [112]. Microlaser welding was successfully demonstrated. Larger laser beam diameters led to undesirable melt filling of the channels. A low power laser diode was used with optical masking and adjusted laser speed to fabricate the weld seams. Laser scan speed of 5 mm/s resulted in 40 μm width seams, whereas 15 mm/s resulted in 10 μm wide seams, which suited the application. As an alternative to laser welding, Truckenmuller et al. utilised ultrasonic welding for joining of polymeric microfluidic devices made from PMMA, and demonstrated that 500 $\mu\text{m} \times 500 \mu\text{m}$ cavities could be welded effectively using energy directors and cavities to guide the melt flow away from the channel [113,114]. Ultrasonic welding of cellulose acetate was investigated by Kim et al. for the fabrication of polymer microfluidics; good sealing was achieved according to preliminary leak tests which used water [115].

Resistance welding has also been used to seal polymeric MEMS. Aluminium thin films were used by Su et al. as built-in or external, reusable resistive heaters [116]. Miniature cavities with a base made of PMMA or PC were bonded to a top layer film of thermoplastic polyvinylidene chloride (PVDC). The quality of this seal was tested using two experiments: one involved placing the bonded

cavity in a vacuum chamber, the other involved immersing the cavity in isopropanol alcohol. Under vacuum, the top of the encapsulated chamber expanded to form a dome-like shape, indicating an airtight seal. The alcohol immersion tests also indicated that there was no leakage into the cavity through the seal. Finally, the cavities were forcefully opened to examine the bond interface. In this assessment the common failure mechanism was substrate failure, indicating a strong bond.

The examples discussed are only a few examples which show how the welding methods presented in the previous section have been applied to fabricate polymeric enclosures. They are however directed toward micro-device applications, and larger scale packages of sizes comparable to cochlear and pacemaker implants are yet to be extensively assessed.

5. Conclusion

The replacement of metals with polymers for encapsulation of active implantable medical devices is an area of interest for research and development. Advantages that polymers offer for this application include ease of fabrication, weight saving, flexibility, electrical and thermal insulation combined with electromagnetic transmission, as well as cost advantages. The remaining challenge that must be addressed for realisation of this potential application of polymers in implantable medical devices is a method for reliable, permanent and hermetic bonding of polymers. Direct bonding techniques for thermoplastics have the potential to change the medical device industry, but the joining technologies will need to be proven using rigorous accelerated test regimes combined with real-time testing to establish the longevity of bond integrity.

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Conflict of interest

The authors have no conflict of interest.

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