Engineering Advances to Reduce Fistula Occurrence in Early Cleft Palate Closure: A Review

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ABSTRACT

Cleft palate repair is commonly done early in life, usually during the first year of life, to facilitate the best speech production and maxillofacial development. Despite these benefits, early closure is linked to a significant risk of postoperative oronasal fistula, a complication that can affect speech, feeding, and overall surgical outcomes. Deficiency of tissue, cleft severity, surgical method, and tension of the wound are all determinants of fistula, which complicates it as a clinical problem. New developments in engineering have introduced new methods to reduce these risks and improve healing outcomes. Precision surgical instrumentation and intra-operative imaging technologies are all forms of surgical engineering that allow for precise flap design and minimization of tension in the closure. Advancements in material science, especially biodegradable scaffolds to reinforce multilayers, improve the incorporation of the tissue and provide temporary scaffolding of the tissue in the healing process. Computational and biomechanical engineering solutions, including finite element modelling, thermal modelling of electrosurgical equipment, and AI-driven predictive analytics, can improve preoperative planning and risk stratification. Engineering solutions for postoperative care, such as smart wound monitoring systems, physical protective systems, and systems for controlled delivery of therapeutic products, may also aid in healing and minimize postoperative complications. Together, these multidisciplinary developments offer strong promise for reducing fistula rates after early cleft palate repair, paving the way for more reliable and functionally successful surgical outcomes.

Keywords: *Cleft palate repair, Oronasal fistula prevention, Surgical tissue engineering, Early palate closure techniques*

1. INTRODUCTION

Palatoplasty is a surgical procedure used to close the cleft in the palate and separate the oral and nasal cavities. The operation is meant to mobilise mucosal and muscular flaps and align them without tension while also maintaining a stable vascular supply so the tissue can heal as a continuous, multilayer closure. When any part of this process fails, closure can break down and form an oronasal fistula (ONF) [1].

A fistula is an opening between the mouth and the nose after cleft repair as a result of failure in primary healing at the suture line post-palatoplasty. It allows air and food to pass between the cavities and requires

secondary surgery and potentially several additional operations to completely fix the cleft, especially in the case of a cleft lip and cleft palate.

There are 4 main underlying causes of ONF [1,2]. The first, and the most researched, is tension on the closure, usually from wide clefts or insufficient flap mobilisation, which mechanically pulls the repair apart. Another is hemorrhage. The excessive bleeding from the damaged vessels separates the tissue layers. There is also post-operative anemia, which reduces oxygen delivery and can slow, or worse, disrupt, the process of wound repair. Lastly, ischemic necrosis, where inadequate blood supply results in flap breakdown.

When to perform palatoplasty is a subject of debate, with the issue of speech development versus maxillofacial growth. Early closure (between 6-12 months) is preferred for normal speech development but presents a heightened risk of ONF. Current literature suggests that ONF rates vary drastically based on the Veau classification of the cleft. For the Veau classification, Veau IV means a bilateral cleft of both the lip and palate; the width of the cleft is not a part of this classification. The reported rates of fistulae for Veau IV clefts are between 12.8% and 23%, while a lower incidence of fistulae is reported in less extensive clefts. The junction of the hard and soft palate is a high-stress zone where the mechanical failure that results in ONF usually manifests [1]. The anatomical distribution of postoperative ONF is illustrated in Figure 1, with fistulas commonly occurring along the palatal repair and particularly around the junction of the hard and soft palate.

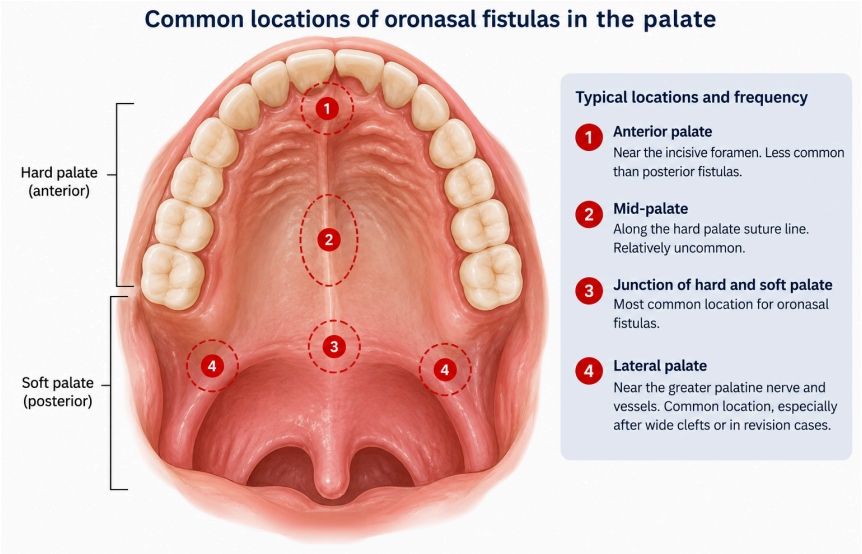


Fig 1. Schematic representation of the palate showing common anatomical regions of postoperative oronasal fistula formation following cleft palate repair.

Excessive tension can lead to raised pressures in the approximated tissue. Small vessels can collapse if local tissue pressure becomes greater than the capillary perfusion pressure (CPP), resulting in decreased

perfusion and increased risk of ischemic tissue breakdown. This review outlines the engineering developments in surgical instrumentation, imaging, materials science, computational modelling, and postoperative care, as well as the potential to address the mechanisms underlying ONF after early cleft palate repair. To combat the mechanical and vascular failures that lead to ONFs, engineering advances have introduced high-fidelity hardware designed to optimize force distribution (to not cause tension).

A narrative literature search was performed in the PubMed, Scopus, and Google Scholar databases. The keywords used in the search were combinations of "cleft palate repair," "palatoplasty," "oronasal fistula," "fistula prevention," "surgical engineering," "intraoperative imaging," "indocyanine green," "laser speckle contrast imaging," "hyperspectral imaging," "robotic surgery," "tissue engineering," "scaffolds," "finite element modelling," "artificial intelligence," "wound monitoring," "arm restraints," and "controlled drug delivery." Literature from 1993 to 2026 was examined and included studies that specifically utilized cleft palate surgery and/or engineering technologies related to the mechanisms of the formation of fistulae. Studies were chosen that were relevant to the review question, technically and/or clinically relevant, and contained adequate information to describe the technology and its use in palatoplasty. Additional evidence from other reconstructive or wound-healing contexts was added when it offers engineering context that is useful, but is distinct from direct evidence for the primary cleft palate surgery.

2. SURGICAL ENGINEERING APPROACHES

2.1 Precision surgical instrumentation

Standard palatoplasty relies heavily on the surgeon's dexterity in a very tight space, where even a minor inaccuracy can affect wound healing. Modern surgical engineering has been very focused on precision, stability, and control, and this priority extends to cleft repair. Precision is very important because intraoperative trauma and poor handling of the tissue are directly associated with flap breakdown and increased rates of ONF.

Microsurgical instruments used in cleft repair have evolved to include ultra-fine tips (< 0.5 mm) and improved designs (ergonomically), allowing for more controlled dissection of the mucoperiosteal flap. These instruments help preserve the integrity of the tissue, which is critical since successful healing depends on maintaining a stable and well-approximated suture line. Excessive trauma at the surgery stage has been shown to increase the likelihood of fistula formation [2].

Another key advancement in cleft repair is the use of electrosurgical devices with reduced thermal spread. Electrosurgery can be used to simultaneously cut and coagulate tissue to minimize intraoperative bleeding and enhance visualization for the surgeon. Electrosurgical energy, however, may also result in thermal damage to the surrounding tissue. Newer low-thermal-spread technologies are designed to confine and distribute heat more precisely, reducing injury to adjacent tissue by preserving vascular integrity, which is essential for flap survival.

Preserving the greater palatine artery (GPA) is one of the most critical factors during palatoplasty. The GPA provides the primary blood supply to the mucoperiosteal flaps, and damage to it can lead to ischemic necrosis and ultimately, failure of the repair.

Intraoperative imaging methods like indocyanine green (ICG) angiography have been investigated in evaluating perfusion in palatal reconstructive surgery. For instance, ICG angiography has been investigated in buccal myomucosal flaps, typically employed in secondary or revision reconstruction, not in routine primary infant palatoplasty [3]. Application to primary infant palatoplasty is less well established, and the safety and ICG dosing in infants should be considered. ICG is a fluorescent dye meant to be injected intravenously, which allows surgeons to visualise real-time blood perfusion under near-infrared light. This allows for the accurate identification of well-perfused tissue as well as early detection of areas with poor perfusion, allowing for immediate correction. Correct and accurate assessment of flap vascularity is of paramount importance to reduce ischemic complications and improve overall healing [3]. Additionally, precision instruments also contribute to better control of the mechanics of the palate during closure. Excessive tension at the suture line is a primary cause of oronasal fistula; instruments that can assist in the controlled mobilisation and positioning of flaps result in a more precise and tension-free closure. Better control during mobilisation of the flap may be helpful to minimise mechanical stress at the site of repair, as excessive tension could lead to failure of repair. Overall, advances in precision surgical instrumentation aim to directly address two of the main failure mechanisms in palatoplasty, those being mechanical tension and ischemia. By minimising tissue trauma through preserving critical blood supply and enabling more controlled handling of the flaps, these technologies play an important role in reducing the incidence of oronasal fistula in early cleft palate repair.

2.2 Intraoperative imaging technologies

A major limitation in palatoplasty is that the assessment of tissue viability is largely based on the visual judgement of the surgeon. Experience plays a significant role in the correct assessment, and this introduces variability and increases the risk of vascular injury. Intraoperative imaging technologies aim to reduce this uncertainty by providing real-time visualisation of blood flow, allowing for more informed decision-making.

One of the most widely adopted techniques is near-infrared (NIR) fluorescence imaging using indocyanine green (ICG) [4]. As discussed previously, ICG angiography enables real-time assessment of tissue perfusion, helping surgeons identify well-perfused areas and avoid areas that are at risk of ischemia. This is particularly important in cleft palate repair, where flap survival is highly dependent on maintaining adequate blood supply from the GPA. Studies have shown that ICG angiography can be useful in assessing flap perfusion during palatal reconstruction and has the capacity to identify poor perfusion in one flap while confirming adequate perfusion in another, informing decision-making and potentially reducing rates of flap necrosis and ONF. Beyond identifying at-risk areas, ICG imaging has shown measurable improvements in outcomes. There is also evidence of the potential value of ICG-guided perfusion assessment from other reconstructive settings. In this retrospective study, the authors evaluated

the outcomes of 877 consecutive free flaps, finding that the partial flap loss rate in the ICG group was 0.45% compared with 5% in the non-ICG group and the re-exploration rate was 3.65% versus 10%, respectively [5]. Free flaps, however, are significantly different than pedicled mucoperiosteal flaps employed in primary palatoplasty and therefore cannot be considered direct evidence of efficacy in cleft palate surgery. In the context of reconstructive head and neck procedures, which share a lot of technical similarities with palatoplasty, the use of ICG fluorescence video angiography has been shown to reduce overall complications from 36.4% to 11.4% and major complications from 30.9% to 8.6%, and has been confirmed to have a "protective effect in univariate and multivariate analyses" [6]. Beyond perfusion imaging, there is increasing use of optical coherence tomography (OCT) as an intraoperative imaging technology. OCT provides high-resolution tomographic visualisation of the subsurface tissue in particular, that conventional en face surgical imaging cannot capture. OCT achieves 1-10 μm axial resolution and, over the last decade, has developed to the use of handheld probes, biopsy needles for minimally invasive deep-tissue imaging, and stereomicroscope-integrated systems that provide real-time three- and four-dimensional visualisation of surgical maneuvers [7].

In the context of graft wound healing, which is similar to the environment of palatal repair, OCT and OCT-based angiography (OCTA) have been used to non-invasively image and monitor the structural and vascular features of skin grafts following reconstructive surgery, having the ability to identify complications early. While OCT is primarily applied in ophthalmology, its expansion into reconstructive surgery reflects a broader trajectory toward real-time tissue-level imaging, which is directly applicable to the palate and the precise nature of its repair.

Another emerging modality is laser speckle contrast imaging (LSCI). LSCI is a non-contact and dye-free imaging technique that measures microvascular perfusion at a depth of approximately 300 μm [8] and can acquire perfusion images over a large tissue area within seconds. In free flap breast reconstruction, LSCI is an effective noninvasive technique for intraoperative mapping of zonal tissue perfusion, with the ability to identify areas of inadequate perfusion and improve decision-making to reduce perfusion-related complications [8,9]. Compared to ICG angiography, LSCI offers practical advantages, including the fact that there is no dye is required, as well as no latency between injection and display, though it operates via a fundamentally different mechanism- capturing a color heatmap of real-time tissue blood flow based on the interference of coherent laser light on red blood cells [10]. However, it is important to note that LSCI is limited to just superficial tissue analysis and cannot be used to identify deeper perforators, meaning it may require complementary modalities for a more comprehensive tissue assessment.

Hyperspectral imaging (HSI) has been applied in pilot clinical trials to assess the viability of free and pedunculated flaps intraoperatively [11,12]. HSI analyzes tissue-light interactions at several wavelengths and applies mathematical models of spectral absorption to estimate parameters like tissue oxygen saturation [11]. It does not require the injection of a fluorescent dye like ICG angiography, but the oxygenation values it gives are still model-based estimates and not direct measurements [12]. In addition, a live porcine laparoscopic study has been performed on real-time quantitative oxygenation imaging, which is indirect evidence for primary palatoplasty [13].

A direct study of infrared thermal imaging has also been investigated in the field of palatal surgery. Tyson et al. [14] presented their experience with using infrared thermal imaging to monitor flap perfusion during revision palatoplasty using buccinator myomucosal flaps in real time. This study is significant because perfusion imaging has not been evaluated in a real surgical setting, as many of the imaging data have been derived from other reconstructive surgical procedures. However, it has not been proven to be effective in primary infant palatoplasty; further studies are needed.

Taken together, ICG, LSCI and HSI represent the evolution of intraoperative imaging technologies, moving away from a subjective visual assessment approach towards an objective, quantifiable and real-time tissue evaluation. In the context of early cleft palate repair, where the level of perfusion can determine whether a repair heals or breaks down into an ONF, the ability to visualise and act on inadequate tissue vascular status intraoperatively is of paramount value. The integration of these technologies into palatoplasty, though still developing, may in time play a meaningful role in reducing ONF rates that result from inadequate perfusion during early cleft palate repair.

2.3 Robotics and Microscope-Assisted Visualization

The other emerging field of surgical engineering in cleft repair is robotic and microscope-assisted systems. The use of robotic instrumentation has been investigated to enhance visualization and manipulation of instruments in the limited space of the oral cavity, but existing robotic instruments are limited in size and access for infant palatoplasty [15,16]. Improved visualization in cleft lip and palate repair has also been achieved using surgical microscopes [17]. More recently, the RoboticScope, a robotic microscope developed to offer hands-free visualization instead of robotic surgical manipulation of tissue, has been tested for primary cleft palate surgery [18]. These are still technologies in their infancy and need to be evaluated in larger trials to see if being able to visualize the processes reduces complications or ONF.

3. MATERIAL SCIENCE ADVANCES TO SUPPORT BETTER HEALING

The failure of palatoplasty repairs to hold is not only a consequence of surgical technique. The palate is a site under constant mechanical load/stress, exposed to saliva, and sitting between two cavities that are permanently separated from each other after the repair (assuming no complications such as ONF), conditions where even a well-executed closure can break down if the tissue lacks sufficient structural support to heal. Therefore, materials science has become an increasingly important area of investigation for ONF prevention, offering supplements that reduce the tension that results in fistula formation. This section summarizes materials-based techniques that could complement palatal closure, such as biodegradable scaffolds, acellular dermal matrices, engineered tissue scaffolds, and tissue adhesives.

3.1 Biodegradable scaffolds for multilayer reinforcement

The standard palatoplasty involves the closure of the nasal as well as oral mucosa, where successful healing depends on bringing these layers together without tension. In practice, this is difficult to achieve

consistently, particularly in cases with a wider cleft with limited tissue available. As a result, tension-free hard palate closure is one of the least reliable areas in terms of long-term surgical outcomes, with fistula rates reported between 0 and 35% [1]. Biodegradable scaffolds aim to address this limitation by introducing an additional structural layer between the oral and nasal flaps. Rather than relying entirely on the suture line to maintain closure, the materials help mechanically support the cleft repair, reducing the burden on the suture line to hold the repair together. The most extensively studied scaffold material in cleft palate repair is acellular dermal matrix (ADM). ADM is formed by removing all cellular components of donor dermis while preserving the extracellular matrix, providing a collagen-rich matrix that promotes revascularisation.

Engineered scaffolds are another option that can be used to strengthen palatal repair. Rizzo et al. created a designed mucoperiosteum scaffold for cleft palate regeneration, which is a non-immunogenic tissue substitute [19]. These scaffolds may also serve to support tissues and help them regenerate. This study, however, does not prove the reduction of the oronasal fistula after primary infant palatoplasty, and further in vivo and clinical studies are needed before this method can be a reliable way of preventing ONF.

3.2 Tissue Adhesives

Another material-based technique is the use of tissue adhesives, which may aid in palatal wound closure. Fibrin-based adhesives can temporarily hold tissue surfaces together and can help to achieve haemostasis and stabilization of the repair. Their use in palatoplasty would be to serve as a complement to the conventional multilayer sutured closure. Evidence to support the ability of tissue adhesives to decrease ONF after primary infant palate surgery, however, is limited. Further clinical studies are needed to see if they have mechanical and haemostatic advantages, which can be linked to reduced fistula rates.

4. COMPUTATIONAL AND BIOMECHANICAL ENGINEERING

A key limitation of palatoplasty in its current state is that planning is almost entirely dependent on intraoperative judgement, with no reliable way to predict how forces will distribute across the repair beforehand. This makes it difficult to anticipate where stress concentrations will occur or where the repair is most likely to fail. Computational engineering approaches aim to address this by modelling the mechanical behavior of palatal tissue, predicting high stress regions and identifying surgical approaches that minimise the risk of potential failure. This section focuses on three main applications: finite element modelling of surgical stress, thermal modelling of electrosurgical devices, and AI and data-driven prediction.

4.1 Finite Element Modeling

Finite element modelling (FEM) is a computational method that divides a complex structure into many smaller elements and calculates how mechanical forces distribute across them, as well as heat transfer and fluid flow. In palatoplasty, this allows simulation of how palatal tissue behaves under surgical conditions, which cannot be directly measured intraoperatively. Three-dimensional FEM models constructed from CT

data have been used to simulate the biomechanics of cleft palate repair by incorporating the material properties of the bone, mucosa, and muscle [20]. The models calculate stress and deformation across incision lines and flap movements to identify regions where tension is highest.

What these models consistently show is that stress is not distributed evenly across the repair. Finite element simulations of both the two-flap technique, which involves raising two mucoperiosteal flaps on vascular pedicles of the greater palatine arteries, and the Furlow double-opposing Z-plasty [21], which stretches the soft palate and repositions the palatal muscles, found that the highest stress concentrations in both techniques occur at the junction of the hard and soft palate, the same region associated with the highest incidence of ONF. This is a significant finding, as it provides an explanation for a pattern that has long been observed surgically but poorly understood mechanically. The models also allow for direct comparison between techniques. Analysis of the two-flap technique suggested that identifying a more optimal fold-over point at the middle suture, where deformation values are lower, could reduce the risk of postoperative complications. Transoral Z-plasty (Furlow palatoplasty), using opposing Z-plasties to lengthen the soft palate and re-position the musculature, was supported by the deformation data as a technique that may significantly improve healing by minimising stress at critical points.

Evidence from FEM studies in other cleft surgeries outside of palatoplasty also shows how the cleft anatomy can impact force distribution. Lee et al. utilized a finite element analysis (FEA) model to analyze the biomechanical effect of orthodontic maxillary expansion in a patient with cleft palate and concluded that cleft anatomy caused asymmetric stress patterns [22]. The results of this study can not be regarded as a direct biomechanical comparison of palatoplasty, but rather as an indirect biomechanical comparison since this study focused on orthodontic expansion.

The key implication is that FEM enables pre-operative planning based on patient-specific biomechanics rather than generalised assumptions. By modelling an individual patient's cleft geometry, it becomes possible to identify high-risk regions before surgery and adapt the repair accordingly, directly targeting the mechanical causes of ONF before they arise.

One major drawback of patient-specific FEM is that accurate anatomical models must be generated from imaging. In infants, a consideration for models generated from CT data is the need for exposure to ionising radiation. However, while patient-specific FEM can be helpful in the planning phase before surgery, it is important to consider the potential benefits of using other imaging modalities as well as the radiation risks involved. Non-ionising imaging techniques should be used when possible.

4.2 Thermal modeling of electrosurgical devices

Electrosurgical devices are widely used in palatoplasty for simultaneous cutting and coagulation. However, the heat they generate does not stay confined to the selected tissue. It spreads to surrounding tissues and compromises local blood supply and can result in ischemic breakdown of the repair. Thermal modelling is the computational approach used to understand and predict how this heat spreads through tissue, to design devices that minimise unintended damage.

Electrosurgery is the use of high-frequency alternating electrical current from 300 kHz to 1 MHz to produce localised heating for cutting and coagulation of tissues. The energy transferred and the mode of application can ensure that the tissue temperature is raised sufficiently to lead to vaporisation, coagulation, and thermal damage to neighbouring tissue [23]. Due to the electric field decreasing with distance from the electrode, steep temperature and pressure gradients form near the point of contact. The consequence of this physics is that the tissue adjacent to the surgical site/area experiences significant thermal stress, even when it is not being directly operated on. In order to minimise this damage, it is of paramount importance to understand how thermal properties of tissues change during the procedure and how those changes affect the extent of the thermal spreading.

Computational models have been developed to simulate this behaviour. A validated thermomechanical model based on mixture theory was used to capture temperature variation in tissue across three different scenarios: no damage at low power, coagulation without cutting at intermediate power, and both coagulation and cutting at high power. While higher power increases the intensity of damage near the electrode, it does not significantly change the width of the surrounding coagulation zone [23]. This has direct implications in palatoplasty. It means that collateral thermal damage to the mucoperiosteal flap is not simply determined by the power setting, and that reducing injury requires a better understanding of the thermal behavior of the specific tissue being operated on.

Feedback-controlled electrosurgery is one way to help minimize unwanted thermal damage. In these systems, the energy delivery can be tailored dynamically depending on measured tissue properties, in addition to a fixed power setting. Changes in the impedance of tissue are utilized as feedback to control power delivery in many commercial electrosurgical systems. The potential application of achieving better control of the energy delivery could minimize unintended thermal spread around significant vascular tissue during palatoplasty procedures, but a direct test needs to be conducted in palatal tissue.

4.3 AI and data-driven predictors

AI and ML approaches take a different angle, using patterns in clinical data to predict which patients are more at risk of poor outcomes, and to assist in the planning and execution of surgery itself.

In the context of cleft lip and palate care more broadly, deep learning models have been shown to improve diagnostic accuracy and support treatment planning. For example, 3D U-Net models have achieved an average accuracy of 92% in estimating alveolar bone grafting volumes, showing how these tools can aid in quantitative planning [24]. Machine learning has been applied to predict which cleft palate patients may require orthognathic surgery during preoperative planning, and deep learning models using convolutional neural networks (CNNs) have been developed to automate nasolabial markings, reducing the reliance on surgeon judgement.

For outcome prediction specifically, AI and machine-learning techniques have shown promising results in various cleft-related applications, including landmark recognition, cephalometric analysis, diagnosis, and

treatment planning [13]. While reported performance does depend on the task, dataset, and model, much of the available evidence is sourced from retrospective or controlled datasets.

A review of AI in cleft care supports that while there is clear potential across surgical planning, imaging, and functional assessment, multicenter studies are still required before widespread use.

A potential application for the future in the context of ONF prevention would be a model that includes preoperative variables like cleft width, Veau classification, patient age, and relevant surgeon-related variables to provide an individual estimate of ONF risk prior to surgery.

5. POST-OPERATIVE ENGINEERING SOLUTIONS

The engineering approaches discussed so far are focused on techniques prioritised during surgery. The period following palatoplasty is equally critical. The repair is most vulnerable in the immediate weeks after surgery, when the tissue is actively healing and has not yet re-established full structural integrity. This window is where a significant number of ONFs emerge from post-operative complications that go unmanaged, not necessarily from surgical error. This section reviews engineering approaches aimed at protecting the repair and supporting the healing environment after the patient has left the operating theater.

5.1 Smart wound monitoring

A fundamental limitation of current post-operative care after palatoplasty is that wound assessment is passive and irregular. The repair is checked at follow-up appointments, and complications are only identified once visible signs appear. At that point, if breakdown has already started, the window for early intervention has already closed. Smart wound monitoring systems take a different approach by continuously tracking changes in the wound environment in real time. The healing site produces biochemical signals, and deviations from regular patterns in pH and temperature, for example, indicate that the repair is beginning to fail.

In smart wound-monitoring systems, pH and temperature are typical parameters investigated [25,26,27,28]. When studying external wounds, alterations in local pH and temperature can occur along with changes in inflammation, infection, and wound healing. But these findings can't be taken directly to the palate. Most reported thresholds for wound pH are based on skin, while the oral cavity is continually in contact with saliva and has a different baseline pH. Therefore, thresholds should be determined for each palate before the use of pH-based sensing could be reliable following palatoplasty.

The engineering challenge here is integrating this capability into a modality that is feasible in a post-operative setting, without being inconvenient for the patient. Smart wound dressings have been developed as an answer that combine embedded sensors and drug delivery systems, allowing real-time monitoring at the wound site. These systems are designed to detect early complications such as infection and inflammation, so that any requirement for intervention is met.

This approach is no longer limited to pH and temperature, and now includes additional measurable parameters. Wearable biosensors can now track pH, temperature, moisture, and infection-related metabolites like trimethylamine and uric acid. These are implemented using flexible electronics, color-changing patches, and electrochemical sensors. This enables non-invasive real-time detection.

Temperature monitoring is particularly relevant. Measuring the difference between the wound site and surrounding tissue provides a useful indicator of vascular behavior. A rise in temperature in the local tissues compared to the surrounding tissues has been investigated as an indicator of infection or inflammation in post-operative wound monitoring [29]. In palatoplasty, reduced blood supply and local infection are two main causes of repair breakdown; detecting these changes before visible dehiscence occurs is very important in preventing failure.

More integrated systems have also been developed. The iCares device, for instance, uses a flexible nanoengineered sensor array that simultaneously measures reactive species such as NO, H_2O_2, and O_2 alongside pH and temperature. This allows a more complete understanding of the state of the wound [30].

There are, however, clear limitations. Early-stage infection only causes small changes in pH and temperature, which makes reliable detection difficult. The palate is also a much more demanding setting than the external wounds these systems are actually designed for. It is constantly exposed to saliva and is mechanically active with every swallow and speech attempt. These factors place significantly greater demands on the stability of the sensor and attachment. Direct application to post-palatoplasty monitoring remains a future potential direction.

5.2 Protective devices

One of the most longstanding postoperative interventions in cleft palate care is the use of physical protective devices such as elbow splints or arm restraints that prevent the infant from bending their arm far enough to place their fingers into their mouth. In the early post-operative period, the repair is held together by sutures. Direct contact with the site could introduce additional stress and disrupt the closure, leading to ONF. Splints are therefore recommended for two to three weeks to prevent this [31].

Despite being widely practiced, the evidence supporting the effectiveness of splints is limited. A randomised study of 46 children having primary cleft palate repair found that arm splints did not decrease the incidence of oronasal fistula, with 6 of 21 children who wore splints and 5 of 25 who did not still developing a fistula post-operatively [32]. Similarly, in a study of 120 consecutive primary cleft surgeries comparing outcomes between a surgeon who used arm restraints in all cases and one who didn't, there was no difference in early complications, including infection or fistula, leading to the conclusion that arm restraints are unnecessary and may cause distress to patients and families [33]. A further study also found no significant difference in complication rates between groups with and without restraints, thus concluding that the literature does not support the use of post-operative splints [34]. A small study found that three out of four fistulas were seen in non-thumb-sucking children [34]. The number of fistulas was very few however, and other bad oral habits such as using a bottle, spoon, or toy are not ruled out by the

absence of thumb sucking. This observation does not conclude that external contact is not important, but it does further contribute to the confusion about the efficacy of routine arm restraints. However, contact with the repair is a possible mechanism of infection as well as additional tension at the suture line.

What this suggests for the engineering of protective devices is that development of said devices may be better directed at reducing intraoral mechanical stress on the repair itself, such as through palatal stenting or mechanical offloading of the suture line. Intraoral protective devices like palatal plates or stents can be used for a more direct approach to engineering, helping to protect the surgical site or to offload the repair. Their effectiveness in preventing ONF following primary infant palatoplasty, however, needs to be directly evaluated in a clinical setting, as any intraoral device requires taking into consideration fit, retention, hygiene, feeding, and airway safety in infants.

5.3 Controlled-delivery postoperative therapeutics

Even a technically sound repair can fail if the biochemical environment of the healing of the wound is inadequate. Reduced oxygen delivery, infection from oral bacteria, and insufficient signalling for tissue regeneration can all disrupt healing independently of what happened during surgery. Controlled-delivery systems aim to address this by placing medication directly at the repair site and releasing it over time [35].

The advantage of local delivery is simple. Blood supply at the wound site is often inadequate, so medication taken orally or intravenously may not reach the repair in enough concentration. These medications can also cause side effects elsewhere in the body, and the inflammation at the wound can break them down before they work. Delivering them directly to the repair avoids these problems by keeping them where they are needed. In the oral cavity, this becomes even more important. Continuous flow of saliva removes topically applied substances.

Poly(lactic-co-glycolic acid) (PLGA) is the most studied material platform for this purpose. PLGA is a biodegradable polymer that has been employed in numerous clinically used and regulatory-approved controlled drug delivery systems [36]. Its mechanical properties and degradation time can be adjusted by adjusting its composition, making it suitable for controlled delivery [36]. For preventing infection, PLGA nanoparticles loaded with gentamicin have been incorporated into films that release the drug in two phases- an initial burst followed by a controlled release. Incorporation of gentamicin-loaded PLGA nanoparticles into films has been developed to give an initial burst and then a more prolonged drug release [37]. This release profile is useful for theoretical postoperative infection control, but it has not been proven after palatoplasty.

The effectiveness of PLGA-based local delivery in an oral mucosal environment is already demonstrated in practice. PLGA-based systems such as Arestin, which delivers minocycline locally, are used in periodontal treatment, which shares key features with the post-palatoplasty wound site. This shows that the material is not only theoretically relevant but has already been validated in practice in a similar context in the mouth [38].

There has been research focused on growth factors, such as VEGF and PDGF, with respect to their involvement in wound healing and tissue regeneration [39]. In principle, pro-angiogenic factors could be delivered locally to benefit revascularisation of healing tissue. This has not been tested in cleft palate surgery. Growth factor delivery and local antibiotic systems like gentamicin-loaded PLGA would need to be carefully evaluated for dose, local and systemic exposure, toxicity, and developmental safety prior to use in the infant. The use of these for palatoplasty should thus be considered as a research avenue and not as a direct extension of clinical use.

Table 1. Summary of Engineering Approaches for Reducing Oronasal Fistula Following Cleft Palate Repair

Technology	**Targeted ONF mechanism**	**Evidence setting**	**Current relevance to palatoplasty**	**Key limitation**
Precision instrumentation	Tissue trauma / tension	Palatoplasty + general surgery	Directly applicable concept	Limited evidence linking specific instruments to lower ONF
ICG angiography	Ischemia / poor perfusion	Palatal reconstruction + free-flap surgery	Emerging	Infant-specific evidence limited
LSCI	Poor perfusion	Reconstructive surgery	Potential	Superficial imaging
HSI	Tissue oxygenation/perfusion	Other surgical settings	Experimental	Limited palatoplasty evidence
Infrared thermal imaging	Perfusion	Revision palatoplasty	Direct but limited evidence	Not established in primary infant repair

Engineered scaffolds	Tissue deficiency / mechanical support	Experimental cleft-palate regeneration	Emerging	Clinical outcomes needed
FEM	Mechanical tension	Computational cleft models	Research/planning	Imaging and validation requirements
AI/ML	Risk stratification	Broader cleft care	Potential	Limited ONF-specific validation
Smart wound sensors	Infection / healing changes	Skin/wound care	Future application	Oral environment differs from skin
Arm restraints	External disruption	Primary cleft surgery	Existing practice	Clinical benefit uncertain
PLGA drug delivery	Infection / healing	Wound and oral drug delivery	Future application	Infant palatoplasty safety/effectiveness untested

6. CURRENT LIMITATIONS AND CHALLENGES

The engineering advances reviewed in this paper represent progress toward reducing ONF rates in early cleft palate repair. However, there are significant limitations, both in the technologies themselves and how they are applied.

The limitation consistent across almost every area reviewed in this paper is the gap between development and application in palatoplasty specifically. Technologies such as ICG angiography, smart wound sensors, FEM modelling, and PLGA-based drug delivery have all been validated in other surgical/wound healing contexts, but direct evidence for their use in cleft palate repair remains limited. The infant oral cavity is a very unique and uniquely difficult surgical site. It is small, wet, mechanically active, and there are oral bacteria present. Technologies that work elsewhere cannot be perfectly assumed to translate without further testing.

A second limitation is the fact that there are no standardized outcome metrics across centres. Different surgical centers measure and report their fistula rates differently. Because there is no agreed standard, it becomes very difficult to compare results between studies. If one paper reports that a technology reduced ONF rates and another reports that it did not, there is no way to tell whether that difference reflects the technology itself or simply the fact that the two centres were measuring fistulas differently. The lack of standard outcome metrics and difficulty maintaining long-term follow-up in reports has been identified as a major barrier to evaluating the success of techniques in cleft palate repair [21].

Technologies like robotic assistance and intraoperative imaging have been shown to reduce the dependence on individual judgement, but they introduce their own problems. The instruments used in robotic surgery are too large for the infant oral cavity and would need to be redesigned before robotic palatoplasty could be safely performed [15]. RoboticScope-assisted palatoplasty also averaged 28 minutes longer than conventional surgery, and larger studies are needed before any conclusions can be drawn [18].

Access is also an important concern as cleft care is needed globally and in low- and middle-income areas where access to specialised surgical infrastructure and emerging technologies might be less available. This means that the patients at highest risk of ONF are also the least likely to benefit from the technological advances reviewed in this paper.

7. CONCLUSION

Oronasal fistula is still a significant complication of early cleft palate surgery. It is multifactorial and can be caused by mechanical tension, impaired perfusion and ischemia, bleeding-related issues, impaired wound healing, and infection, which can lead to breakdown of the repair. This review demonstrates that engineering is actively developing solutions that target each of these mechanisms directly.

Precision surgical instrumentation and intraoperative imaging technologies such as ICG angiography address the two main intraoperative failure mechanisms, those being tension and ischemia, by improving how surgeons handle tissue and assess blood supply in real time. Biodegradable scaffolds and tissue adhesives provide structural support to the repair itself. Experimental techniques like finite element and thermal modelling offer additional ways to study the distribution of mechanical stress and heat in tissues and can eventually be used to enhance surgical planning and device design. However, there is no standard routine use of them in infant palatoplasty. AI-based tools, although in their formative years, are beginning to offer patient-specific risk prediction. Post-operative solutions aim to protect the repair during the healing window post-surgery.

However, the gap between what has been developed and what has actually been tested in the specific context of palatoplasty remains quite large. Most of these technologies are certainly promising but not yet established in this specific context. Closing that gap and ensuring that advances are accessible beyond settings with greater resources are the most important challenges that remain.

8. FUTURE PERSPECTIVES

As for future perspectives, the most immediate priority is validation within the specific context of palatoplasty. The majority of technologies reviewed in this paper need to be tested specifically in palatoplasty before they can meaningfully contribute to reducing ONF rates. This includes ICG angiography applied directly to palatal flap assessment, and FEM modelling built from infant-specific data rather than adult data.

Individual technologies such as imaging, computational modelling, AI risk prediction, and controlled drug delivery each address each part of the problem. A system that combines patient-specific FEM planning before surgery, real-time perfusion imaging during surgery, and postoperative monitoring after surgery would address each failure mechanism of ONF simultaneously.

Finally, any future advance needs to be designed with accessibility in mind from the start. Cleft palate is most common in parts of the world where the most sophisticated technologies are least available. Engineering solutions that cannot be deployed outside of the best-funded centers will not reduce global ONF rates in any meaningful way.

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CONFLICT OF INTEREST

There is no potential conflict of interest to disclose.

AUTHOR'S INFORMATION

DP conceptualised the study, did the literature survey, and wrote and edited the manuscript.

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