

Review Article

Clinical Utility of Integrant's FrameIt

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Citation: Bachmid Z, et al. Clinical Utility of Integrant's FrameIt. Jour Clin Med Res. 2024;5(2):1-8.

<https://doi.org/10.46889/JCMR.2024.5202>

Received Date: 22-04-2024

Accepted Date: 19-05-2024

Published Date: 27-05-2024



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Abstract

This paper explores Integrant's FrameIt, a novel external fixator based on the Taylor Spatial Frame (TSF). The TSF, invented by Dr. Charles Taylor, offers significant advantages over traditional Ilizarov frames in treating complex bone deformities and fractures. FrameIt leverages the TSF's ability for precise six-axis adjustments and computer-assisted planning to achieve faster correction times and improved patient outcomes.

The paper delves into the TSF's background, highlighting its development as a solution to the limitations of the Ilizarov frame. It emphasizes the TSF's reliance on principles from projective geometry, the Chasles' Theorem and the Stewart Platform to achieve its superior accuracy.

Furthermore, the paper explores the factors impacting the TSF's success. It analyzes the influence of:

- Available and Emerging Technologies: The paper stresses the importance of utilizing advancements enhancing the TSF's design and functionality
- Historical and Cultural Factors: The paper acknowledges the historical context that led to the development of external fixation systems, with the Ilizarov frame paving the way for the TSF
- Economic Factors: The paper discusses the economic considerations surrounding the TSF's adoption, including equipment costs, procedures and aftercare. It highlights the limitations imposed by high costs on accessibility for some patients

In conclusion, the paper positions Integrant's FrameIt as a promising advancement in bone deformity correction. By building upon the TSF's foundation and addressing economic barriers, FrameIt has the potential to revolutionize patient care in this field.

Keywords: Ilizarov Frame; Taylor Spatial Frame; External Fixator; Complex Fractures; Osteotomies; Chasles' Theorem; Stewart Platform; Projective Geometry

Introduction

Integrant's FrameIt is based off the Taylor Spatial Frame (TSF) (Fig. 1), which is a hexapod external fixator, implemented by paediatric and orthopaedic surgeons to treat bone abnormalities and multifaceted fractures [1]. This device has a unique ability to correct complex deformities and make highly precise adjustments from 6 different along with being able correct deformities on 3 planes consisting of length angulation and rotation, coupled with its computer-assisted planning software, allowing for precise adjustments and more successful outcomes, reducing treatment time (up to 6 months of recovery) [2]. The device has made substantial modifications in patient outcomes allowing for effective deformity correction and more mobility and convenience for patients during correctional processing, improving patient quality of life. This can be seen in a study completed by Slater and Bachmid which a patient was able to return to work as a fully operational Police Force member with great mobility in the ankle compared to the other alternatives [3]. An X-Ray is shown of the patient with the FrameIt along with adequate space in the joints after removal in Fig. 2.



Figure 1: Integrant's FrameIt based on the Taylor Spatial Frame.



Figure 2: Patients X-Ray during with FrameIt and X-Ray following the removal [3].

The apparatus leverages the body's natural ability to grow healthy cartilage and connective tissues, gradually rebuilding and moving bones to lengthen limbs, correct limb deformities and relocate fractured and or broken bones, that can be seen in a variety of studies [4]. The frame contains two or more partial or full rings, made of aluminium and carbon fibre, linked by six rods called telescopic struts, seen in Fig. 1. The struts can be lengthened or shortened as needed, connected to the rings to enable multi-directional movement using a virtual hinge, allowing for lengthening, shortening, angulation and rotation of bones into almost any position simultaneously. The rings and struts come in many sizes and shapes to fit various limb sizes and shapes. The frame fits around your limb and is attached to the bone with pins or wires that come out of the rings, through the skin and bone to the other side. It is then attached through an osteotomy, a surgical procedure in which the surgeon places an incision on the bone. The pins and wires are then attached to apply the frame and stabilize the limb while the correctional processing takes place. The adjustment for the device is used, most commonly for distractions where the standard procedure is to distract 1 mm per day [5]. Unfortunately, the areas in which the pins are inserted into the bone are prone to infection, affecting up to 20% of patients, however, this fault does not outweigh its 87.95% success rate [6,7]. If the definition of infection is considered as only occurring if redness is persisting after 72 hr, spreading erythema, temperature increase, pain (nb beware charcot patients) and or purulent discharge than infection with an appropriate resume should fall well below 5% [8]. These infections can be classified in 6 different levels seen in Table 1. Each level will have a treatment option and the higher the level the more invasive the treatment will be [8].

Level of Infection	Symptoms	Treatment Method
Grade 1	Slight redness around the pin. Minimal discharge. Should improve with proper care and hygiene. Can progress into serious infection.	Increase level of cleaning and perform massaging to prevent pin adherence. Ensure wound is appropriately draining and remove crusts.
Grade 2	Skin redness, discharge and pain in soft tissues.	Administer oral antibiotics. Oral antibiotic depends on the bacteria, which is usually <i>Staphylococcus aureus</i> .
Grade 3	Grade 2 infections that continue despite improved care and oral antibiotic.	Administer intravenous antibiotics. Pins potentially re-sited. External fixation continues.
Grade 4	Severe infection that involves multiple pins. Pins may be loosened.	The pin is removed. External fixation is discontinued.
Grade 5	Tissue is infected and bone may be involved. Osteolysis and sequestrum formation is present from radiographs.	Infected tissue is removed surgically to prevent the spread of infection. Will resolve after fixator removal.
Grade 6	Chronic osteomyelitis (infection of the bone).	Typical treatment will involve debridement or treatment through antibiotic agents. Can lead to long-term disability and discomfort.

Table 1: Symptoms and treatments of varying grades of pin site infection [8].

Background of the TSF

The TSF was invented by Dr J. Charles, his engineer brother and medical professionals in Perth Australia in 1994 [9]. The inception of the device would provide patients with improved results globally, concentrated healing periods and amplify accuracy in bone deformation. This is especially when compared to a standard Ilizarov frame which require intricate planning and evaluation and meticulous adjustments with the fixator [10]. However, the adjustment of the Ilizarov frame can be considered laborious and error prone, hence the gap of the Ilizarov frame being the reason of inventing the TSF, implementing the principles of projective geometry, the Chasles' Theorem and the Stewart Platform to overcome these challenges [11]. Projective Geometry examines the relationships between geometric figures and the images that result from projecting them onto another surface [12]. This principle enabled the TSF to precisely manipulate bone segments in ways traditional methods and the Ilizarov frame cannot. The interference fit of the frame would mean there is less movement within the leg and frame, leading to less movement, furthermore, leading to less infection [15]. The Chasles' Theorem is a kinematic theorem that states the most general inflexible body dislocation can be produced by a transformation along a line followed by a rotation about an axis parallel to that line [13]. This theorem is crucial in understanding bone deformities and how they can be corrected with minimal alterations by pinpointing a sequence of movements that can relocate the bones precisely, ultimately streamlining the correctional process and decreasing the potential for error. The Stewart Platform is a parallel manipulator with six prismatic actuators, paired and connected between three positions on a baseplate and three mounting points on the top plate [14]. The Stewart Platform exemplified how perfected corrections can be made to the spatial orientation of bones. Moreover, implementing these principles in the design process of the TSF, opened doors for orthopaedic surgeons to efficiently and accurately correct complex deformities using the TSF. A complicated fracture is shown in Fig. 3 and how the use of the Frame can be used to heal it.

The FrameIt further improves the lock mechanic in then hard wire frame system. This allows for multiple passages of hard wires at 2.7 mm. Steinmann pins not required, hence there is less movement within frame meaning less infection and less pain according to the Chaos theory [15]. This can add to the utility, also it is easier to apply as wire tensing not required. The Framelt would support the bones with their wires rather than cutting like other frames.

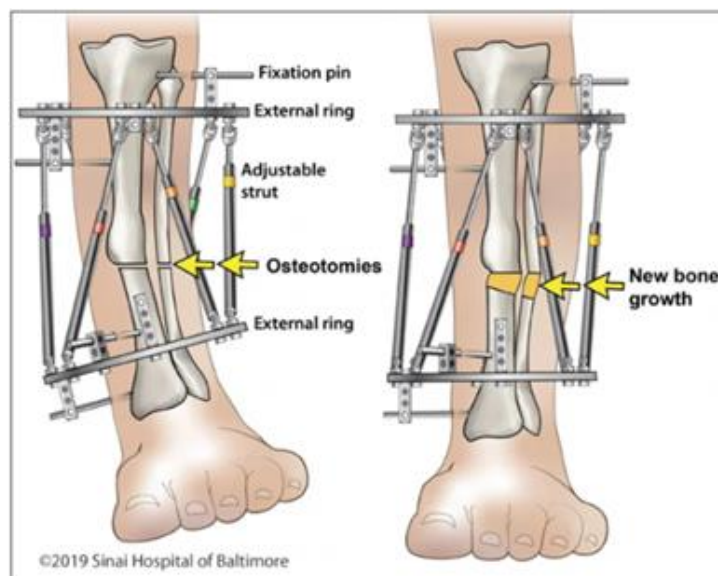


Figure 3: Correctional Process of a Complicated Fracture.

Factors Impacting the Success of the TSF

Available and Emerging Technologies

Utilising available and emerging technologies is crucial in determining the success or failure of an innovation. Available and emerging technologies are tools that are still within their development stage or that are predicted to be accessible within the next 5 to 10 years and are usually reserved for technologies that are generating or expected to generate significant social or economic effects [16]. These technologies are mostly new but can be older technologies with new applications and are found through research, assessments and monitoring trends. For designers to remain ahead of their competition, consistent innovation of emerging technologies is crucial in enhancing flexibility, serviceability and aesthetics of their product design. Without careful consideration of emerging technologies in the creation of an innovation, the success of the product can be greatly tarnished. The neglect of modern technology can result in, a loss of competitive edge, reduced efficiency and productivity an inability to meet customer expectations and an overall decline in the innovation's market relevance [17]. However, if considered the innovation's capacity to engage customers through met expectations, gain a competitive advantage over other innovations and remain stable in its market relevance, is attainable. Additionally, emerging technology holds a grave responsibility and impact on modern day medicine, affecting the ways in which doctors and medical professionals operate now and in the future [18]. Although numerous medical technologies have been about for years and are in the endless process of progress, AI has been one of the most impactful in this field. Overall, emerging technologies are crucial in the design process of innovations to enhance its success and relevance, demonstrating an evident growth in modern medicine. In comparison to the other external fixators currently such as the Ilizarov frame, according to a study the DCT for the TSF was shorter than the Ilizarov frame due to its higher degree of deformity collection [19].

Historical and Cultural

Cultural and historical factors are crucial to ensure social acceptance, product success and establish a genuine need for the launch of a product. For innovations to be successful the innovator must consider the historical and cultural environment. Considering cultural factors in the production of a design means recognising and incorporating the cultural nuances, preferences and ethics of the target audience [19]. Understanding people's beliefs and practises is an essential step in the introduction of an innovation as it allows for the launch of a product that resonates with the target audience's morals and wants, guaranteeing a more positive response and acceptance of the innovation. Without adequate analysis of the social implications of a product, designers can tarnish their reputation, lose customers and profits [20]. Innovations are built upon the foundations of historical innovations. Many technological advancements and innovations would not be available without the assistances of inventors and innovators of the past. Exemplifying the significance of acknowledging and crediting these efforts to identify a genuine need for an innovation [21]. By building upon these foundations set by past inventors, we can continue to push the limits of what is possible and produce a better world for ourselves and future generations. Ultimately, cultural and historical factors are a vital consideration in the launch of products, enhancing acceptance of a product and guide the development of new innovations.

Although the TSF does not have a specific interaction with cultural factors, its history developed the need for external fixation systems. The TSF was not invented in response to a specific historical event but rather as a technological advancement of the Ilizarov frame. Through Dr Taylor's critique of the Ilizarov frame he identified its shortcomings, allowing him to develop an improved technologically progressive version that leveraged its success. Building upon Gavril Ilizarov's foundation, its essential to understand the historical context in which the frame itself was invented highlighting the challenges of its time it aimed to address. Gavril Ilizarov developed his Ilizarov frame in Siberia, serving to treat veterans following the second world war [22]. In Siberia, Ilizarov's work was pivotal in addressing the complex fractures and injuries sustained by veterans. This cultural significance can be seen with Ilizarov having a postage stamp after him seen in Figure 4. At the time, Canadian orthopaedic surgeon Dror Paley, wanted to learn Ilizarov's and bring Ilizarov's techniques to North America, but tensions in the Cold War era Soviet Union made it challenging for Western medicine to gain access to this "closed" Soviet city [23]. Ilizarov wanted to share his method with an American audience but was wary of not receiving adequate credit given the secrecy between the two nations. Paley helped to ease these tensions by being able to communicate with Ilizarov in Russian. Eventually, the Ilizarov procedure of Transosseous Osteosynthesis was booming by the 1980's [24]. This wartime necessity for orthopaedic solutions solidified the emergence of the Ilizarov frame making it the keystone in the path of external fixation systems, paving the way for the sophisticated TSF. Moreover, the success of the TSF is intricately woven into the history of the Ilizarov frame which itself emerged as a vital solution during the challenges of post WWII, sparking technological advancements in external fixation devices.

Cultural factors may affect the interest in the stakeholder's willingness to use the TSF. The patient's attitude towards disabilities may divert them from using the frame as they may view the limitations associated with it. In conjunction, the patient maybe worried about the aesthetic of the frame, while others would prefer the functionality of the frame. Socioeconomic factors play a major role to the use of the frame. This can include access to healthcare, along with access to the frame itself. Financial constraints can create a barrier for use with the frame as it can be an expensive procedure.



Figure 4: Ilizarov in a Russian postage stamp in 2021.

Economic

Contemplation of economic factors is substantial in determining the success or failure of a product. Economic factors designers should consider include interest rate, inflation, tax rate and employment, all of which affect the consumer demand [25]. Adequate analysis of one's target demographic and their socioeconomic status is crucial for effective market positioning and pricing strategies. A growing economy is occasionally good for designers of new products, as consumers are more enthusiastic to spend money and try new concepts [26]. Consequently, financially secure consumers assume quality and sophistication in their products and will not accept goods that do not meet expectations. A declining economy may also affect innovation, as products must become more efficient [26]. In relation to innovative medical devices, understanding the economic field assists innovators to evaluate the affordability of their innovation for both healthcare providers and patients [27]. This reflection is vital to ensure extensive accessibility and acceptance. Overall, innovators must evaluate economic factors in the creation of their innovation to guarantee market accessibility and affordability.

Economic factors have played a significant role in the success of the TSF through the cost of the equipment, cost of the procedure and aftercare costs. Once purchased, surgeons and supporting medical staff undergo training the apparatus is used proficiently following the principles of the device, application and treatment protocol. The cost of purchasing the equipment by the Hospital is \$10,675 however the procedure cost for patients is \$19,138. According to a comparative study by PubMed, an American resource database, comparing the financial complications of the TSF and the Uniplanar external fixator, the equipment cost and treatment of the TSF deemed 'cost-conscious' [28]. Although procedure and equipment costs can vary depending on the hospital, country it is done in and the complications being resolved, the costs after surgery combat this. The TSF stays on for up to 6-12 months during bone correction, during this time infection can occur, psychological damage can develop and patients must learn to adapt to everyday routines with the frame as walking with the frame isn't immediately supported [29]. This can lead to other costs such as wheelchairs, crutches, clothes that are adaptable with the frame and pin site care equipment to reduce chance of infection and these costs are seen in Fig. 5. Although these financial implications didn't greatly impact the success of the TSF as, it is still innovative and holds a high success rate, they do pose challenges for those who cannot afford the procedure, limiting its market penetration. However, the Consumer Health Forum of Australia highlights a broader concern, being medical devices are 30%-40% more expensive than other countries [30,31]. Therefore, these issues do not lie in the distribution of the apparatus but the medical framework it is constructed by, limiting its success as the market is narrow. Moreover, whilst economic factors shape the success and availability of the TSF, the issue lies within the healthcare system, limiting the market and accessibility to patients.

Equipment item	Hire Cost approx.
Wheelchairs – adult size	\$35p/w
Wheelchairs - for small children <8yrs (14 or 16inch)	\$35p/w
Ask for seatbelt	
Wheelchairs with leg raisers	\$50p/w
Ask for seatbelt	
Slide boards	\$10p/w
Rollator frames	\$9p/w
Rollator frames for small children <8yrs (ie 70cm tall)	\$10p/w
Gutter frames	\$25p/w
Gutter frames for small children	\$25p/w
Static commode chair	\$25p/w
Wheeled commode chair	\$20p/w
Wheeled commode with leg raisers	\$28p/w
Lifter	\$55w
Sling (for lifter)	\$10p/w
Hospital bed	\$65p/w
Ramps for house access	\$25p/w per ramp *dependant on size occupational therap

Figure 5: After care costs of Ilizarov frames.

Conclusion

The Integrant's FrameIt, based on the Taylor Spatial Frame (TSF), offers a significant advancement in treating complex bone deformities and fractures. Compared to traditional methods, the FrameIt provides several advantages:

- **Precise Adjustments:** The FrameIt allows for highly precise adjustments on multiple planes (length, angulation, rotation) due to the measurements available
- **Faster Recovery:** Treatment times are reduced compared to traditional methods, with patients potentially returning to work within 6 months
- **Improved Patient Outcomes:** The FrameIt facilitates effective deformity correction and increased mobility during treatment, leading to a better quality of life for patients

Despite potential pin site infections, the FrameIt boasts a high success rate (over 87%) [7]. The device builds upon the legacy of the Ilizarov frame, addressing its limitations through advancements in design principles. However, economic factors can limit the FrameIt's accessibility. The cost of the equipment, procedure and aftercare can be a significant burden for patients and

healthcare providers. Addressing these economic challenges can further broaden the FrameIt's impact and improve patient access to this innovative technology. The stakeholders of the FrameIt adds to the economic factors which consist of the orthopaedic surgeon, physical therapist, nurse and patient itself. The orthopaedic surgeon will apply the FrameIt, making the distraction process simpler and more accurate for the surgeon. However, compared to an Ilizarov frame the equipment maybe expensive in comparison. The physical therapist will aid rehab the patient's movements, which may happen within the frame, but has minimal to no change for the therapist. The nurse is involved in the pre- and post-operative care including wound and pain management. The earlier studies show a reduction in pin site infection and pain with the FrameIt, alleviating pressure from the nurse. The patient will have a faster recovery time, less pain and less infection chance being an advantageous choice compared to an Ilizarov frame.

The research within this study may have some limitations which do include having specific cases for the success of the FrameIt. The conclusions drawn from this study may be different for some individuals as they may be from a different demographic to the studies used in the paper. Hence, further research on the FrameIt with a larger demographic can help create more accurate research.

Conflict of Interests

Dr. Gordon Slater has a pecuniary interest in Integrant a biotechnology company and Regen U clinics where he actively advises on treatment protocols and implant design.

Acknowledgement

Acknowledge those who provided technical support during the study.

Financial Disclosure

No funding was not involved in the manuscript writing, editing, approval or decision to publish.

Authors Contribution

Writing of the paper: Mr Zadane Bachmid / Miss Adelaide Slater

Research on TSF: Miss Adelaide Slater

Research on FrameIt and Clinical studies: Mr Zadane Bachmid

Proofreading/Editing of the paper: Dr Gordon Slater

Data Availability

Data is available for the journal. Informed consents were gained from the patients.

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