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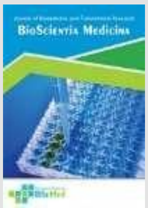

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Modular Megaprosthesis as a Definitive Salvage Strategy for Recalcitrant Distal Femoral Non-Unions: A Biological and Mechanical Reset in the Hostile Environment

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A B S T R A C T

Background: The management of recalcitrant distal femoral non-unions characterized by massive bone loss and exhausted biological potential presents a formidable challenge in orthopedic surgery. This study evaluates the early functional outcomes and safety of modular knee megaprostheses as a radical salvage strategy, utilizing oncologic reconstructions as a benchmark for comparative analysis. **Methods:** A descriptive case series of eight consecutive patients, including six oncologic and two non-oncologic cases, was conducted between December 2022 and March 2025. Non-oncologic cases involved elderly patients with a mean age of 48.5 years and multiple failed prior fixations. A standardized infection rule-out protocol was strictly applied, involving serological markers and joint aspiration. Functional outcomes were quantified using the Musculoskeletal Tumor Society (MSTS) score with a mean follow-up of 14.8 months. **Results:** The mean MSTS score across the cohort was 20.2 out of 30. Non-oncologic patients demonstrated lower physical performance scores, averaging 18.5 compared to 20.8 in the oncologic group, primarily due to long-standing disuse atrophy and age-related confounders. However, these patients reported significantly higher emotional acceptance, averaging 4.5 out of 5, following the immediate restoration of limb stability. No acute periprosthetic infections or mechanical failures were observed within the short-term follow-up period. **Conclusion:** Megaprosthesis serves as a viable biological and mechanical reset for complex non-unions, converting a failed biological healing process into a reliable mechanical solution. While the procedure requires rigorous infection screening and carries long-term risks, it offers immediate stability and transformative pain relief in elderly or multiply-operated patients.

1. Introduction

The management of segmental bone defects in the distal femur represents one of the most complex frontiers in reconstructive orthopedics, traditionally governed by two divergent surgical philosophies.[1] On one hand, traumatic bone loss has historically been addressed through biological reconstruction, an approach that prioritizes the preservation and restoration of the patient's own skeletal tissue through methods such as internal fixation, bone grafting, or distraction osteogenesis. On the other hand, oncologic resections for primary bone malignancies have relied upon endoprosthetic replacement, where the primary goal is the immediate restoration of structural integrity following the removal of diseased bone. However, a growing clinical intersection has emerged in the form of the recalcitrant distal femoral non-union, a condition that frequently defies these traditional boundaries.[2]

The recalcitrant non-union is defined not merely by a lack of radiographic bone healing, but by the establishment of a hostile environment. In these scenarios, the biological landscape is characterized by exhausted regenerative potential, often the result of multiple failed attempts at internal fixation.[3] Each subsequent surgery leaves a legacy of scar tissue, compromised vascularity, and regional osteopenia. The presence of retained or failed hardware further complicates the site, often acting as a scaffold for subclinical biofilms and further inhibiting the natural inflammatory pathways required for fracture repair. In such hostile environments, the fundamental physiological requirements for traditional fracture healing—summarized by the diamond concept of a stable mechanical environment, adequate blood supply, osteoinductive signals, and osteogenic cellular potential—are often profoundly absent. The bone ends frequently become sclerotic and avascular, creating a biological dead zone where the metabolic activity necessary for callus formation cannot be sustained. For the patient, this results in a state of chronic instability, persistent pain, and progressive functional decline.[4]

Traditional biological salvage options for these complex cases carry significant morbidity. Methods such as the Masquelet technique, massive autologous bone grafting, or the use of circular external fixators like the Ilizarov apparatus are technically demanding and require an exceptional degree of patient compliance. These procedures typically necessitate prolonged periods of non-weight-bearing, often extending for twelve to eighteen months or more, to allow for the slow process of biological incorporation and remodeling.[5] For elderly patients or those burdened by multiple comorbidities, such as diabetes mellitus or peripheral vascular disease, these biological solutions are poorly tolerated. The systemic stress of multiple operations, combined with the physiological toll of long-term immobilization, frequently leads to complications such as deep vein thrombosis, pressure ulcers, and pneumonia. In many instances, the failure of these biological attempts results in persistent disability, institutionalization, or eventual limb amputation, which carries its own significant mortality risk in the elderly population.

The modular knee megaprosthesis, originally designed for the massive resections required in the treatment of bone sarcomas, offers a radical alternative to biological salvage. By utilizing an endoprosthetic approach, the surgeon essentially bypasses the requirement for fracture callus formation entirely. The diseased, non-union segment is resected, and the biological problem is substituted with a predictable mechanical interface. This biological reset allows for the immediate restoration of limb length and alignment, utilizing the healthy bone proximal to the zone of failure for stable, often cemented, fixation.[6] The modularity of modern systems allows for precise reconstruction of the segmental defect, while the rotating-hinge design addresses the ligamentous instability that often accompanies chronic distal femoral non-unions. This approach offers the profound advantage of immediate weight-bearing, which is critical for the maintenance of muscle mass and the prevention of the systemic complications associated with immobility. Despite its potential to offer immediate stability, clinical data regarding these trauma bail-out procedures remain sparse in the literature.

This lack of robust data exists primarily because trauma surgery and orthopedic oncology are typically treated by distinct surgical sub-specialties that operate in silos. Trauma surgeons, while experts in fracture fixation, may lack familiarity with the long-term management and failure modes of oncologic megaprostheses.[7] Conversely, oncologic surgeons, while adept at massive reconstructions, may not frequently encounter the specific challenges of latent infection and poor soft tissue quality inherent in multiply-operated trauma patients. At our institution, we have addressed this gap through a unique, multidisciplinary Orthopedic Oncology-Trauma Team approach. This collaboration allows for the cross-pollination of specialized techniques, combining the rigorous infection screening and reconstructive expertise of oncology with the functional rehabilitation focus of trauma surgery. By integrating these perspectives, we can better navigate the complexities of the recalcitrant non-union, ensuring that the mechanical solution is tailored to the unique biological and psychological needs of the trauma patient.[8]

A critical component of this study is the exploration of patient-reported outcomes, specifically what we identify as the satisfaction paradox. In orthopedic oncology, patients often experience the reconstruction as a loss; they are typically young, previously healthy individuals for whom the surgery represents a life-altering trauma and a reminder of a cancer diagnosis.[9] Consequently, despite having better physical function, their emotional acceptance scores may be relatively low. In contrast, patients with recalcitrant non-unions have often spent years in a state of chronic disability, relying on braces, crutches, or wheelchairs for basic mobility. For this population, the immediate stability provided by a megaprosthesis—even if it results in a lower physical score compared to a healthy limb—represents a transformative triumph of independence and a relief from chronic pain. Understanding this disparity is essential for counseling patients and for defining what constitutes a successful outcome in complex limb salvage.[10]

This study aims to describe the early functional outcomes and safety signals of modular knee megaprostheses in complex, recalcitrant distal femoral non-unions, utilizing a cohort of oncologic reconstructions as a benchmark for comparison. We seek to evaluate the efficacy of a strict infection rule-out protocol and the functional recovery as measured by the Musculoskeletal Tumor Society score at a mean follow-up of 14.8 months. The novelty of this research lies in its conceptual framing of the megaprosthesis not merely as a replacement, but as a biological reset for the hostile non-union environment. Furthermore, we aim to formally identify and describe the Satisfaction Paradox, providing a more nuanced understanding of how patient expectations and prior disability influence the perception of surgical success. Through this descriptive series, we intend to provide clinical evidence for the megaprosthesis as a definitive salvage option in elderly or multiply-operated patients where biological healing is no longer a viable goal.

2. Methods

This research was structured as a retrospective descriptive case series, encompassing eight consecutive patients who underwent limb salvage with modular hinged knee megaprostheses at a single tertiary orthopedic center. The study period, spanning from December 2022 to March 2025, represents a critical timeframe during which our institution refined the collaborative oncology-trauma approach. Given the complexities of treating recalcitrant non-unions with oncology-grade hardware, institutional ethical oversight was strictly maintained. Institutional Review Board approval was obtained, and all patients provided written informed consent prior to data collection, ensuring that the use of their clinical and radiographic data adhered to the highest standards of patient privacy and ethical transparency.

The inclusion criteria were specifically tailored to isolate cases of massive bone loss and recalcitrant failure, where conventional orthopedic methods had reached their biological and mechanical limits. Patients were eligible for this series if they presented with distal femoral bone loss exceeding 5 centimeters, a threshold often cited as the transition point where traditional bone grafting or fixation becomes highly unpredictable. For the non-union cohort, a minimum of two failed prior surgical attempts at osteosynthesis was required, ensuring the study focused on patients with truly exhausted biological potential. A minimum follow-up of three months was established to capture early functional recovery and acute safety signals.

Conversely, exclusion criteria were implemented to minimize confounding variables that could skew early functional outcomes or compromise safety. These included active systemic infection, which would necessitate a multi-stage approach rather than a single-stage reset, and a Body Mass Index (BMI) exceeding 40, as extreme obesity significantly increases the mechanical stress on the bone-cement interface and heightens the risk of wound complications. Furthermore, patients documented as unable to comply with the post-operative weight-bearing and physiotherapy protocols were excluded to ensure the functional scores reflected the procedure's potential rather than poor rehabilitation adherence.

Perhaps the most critical phase of the biological reset is the systematic identification of latent infection, which is often the silent cause of recurrent non-unions. Our protocol recognized that many non-unions are not merely structural failures but are plagued by subclinical biofilms sequestered on old hardware. To address this, we implemented a mandatory, multi-tiered preoperative screen: (1) Serological Screening: Baseline erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels were obtained for every patient. While often non-specific, persistent elevations in these markers served as red flags for further investigation; (2) Joint Aspiration and Synovial Analysis: All patients underwent preoperative joint aspiration to obtain synovial fluid for white blood cell (WBC) count and differential. This provided a direct biological window into the intra-articular environment, allowing for the differentiation between aseptic mechanical failure and indolent infection; (3) Intra-operative Frozen Section Analysis: In cases where preoperative suspicion remained high—even with negative serology—a frozen section was performed during the reset resection. The presence of more than five neutrophils per high-power field was used as the diagnostic threshold to determine whether to proceed with a single-stage megaprosthesis or pivot to a temporary antibiotic spacer.

The surgical philosophy focused on converting an unpredictable biological environment into a stable mechanical construct. All procedures were performed by a senior orthopedic oncology team, specialized in the massive soft-tissue and bone resections required for megaprosthetic placement. The selection of the implant was paramount. We utilized a modular rotating-hinge knee system for all cases. Unlike a fixed-hinge design, the rotating-hinge mechanism allows for a degree of axial rotation, which significantly reduces the torsional shear forces transmitted to the bone-cement interface. This is particularly critical in trauma patients who, once their pain is relieved, may return to higher levels of activity than traditional oncology patients.

To facilitate immediate mobilization, fully cemented stems were used in all eight patients. This choice allows for immediate partial weight-bearing, bypassing the months of immobilization required for biological ingrowth systems. In the non-union cohort (P4 and P8), the cement was specially formulated as a dual-antibiotic carrier containing both Gentamicin and Vancomycin. This provided a localized, high-dose eluting antimicrobial shield directly at the site where previous biofilms may have existed.

Finally, the extensor mechanism and patellofemoral joint were addressed with precision. In the distal femur resections, the quadriceps mechanism is generally preserved; however, patellar resurfacing was performed in 75 percent of cases. This decision was guided by the degree of chondromalacia observed during the biological reset resection, ensuring that the reconstructed knee did not suffer from secondary patellofemoral pain, which could hamper the patient's walking ability and final functional score. This comprehensive approach ensured that every component of the hostile environment—biological, mechanical, and infectious—was systematically addressed during the single-stage reconstruction.

3. Results

Table 1 delineates the comprehensive demographic and clinical profiles of the eight patients included in this pilot series, highlighting the fundamental heterogeneity between the oncologic and non-oncologic cohorts. The study population is bifurcated into six primary oncologic cases and two recalcitrant non-union cases, reflecting a significant disparity in age and surgical history. The oncologic group, comprising patients with giant cell tumors or Osteosarcoma, represents a younger demographic with a mean age of 30.5 years. In stark contrast, the non-oncologic cohort consists of older individuals with a mean age of 48.5 years, who have endured multiple failed attempts at osteosynthesis before being considered for a definitive mechanical bail-out procedure.

The clinical history of the trauma patients, particularly Patient 4 and Patient 8, underscores the concept of biological exhaustion that characterizes the hostile environment inherent in chronic distal femoral failures. These individuals presented with a history of three and four prior operations, respectively, indicating a repeated failure of conventional fixation and the presence of significant segmental bone loss exceeding five centimeters. Furthermore, the presence of systemic comorbidities such as Type II Diabetes Mellitus, smoking history, and hypertension in the non-union group adds a layer of physiological complexity that often precludes successful traditional biological reconstruction.

The follow-up duration averages 14.8 months across the series, ranging from 4 to 26 months, which captures the early postoperative outcomes and functional grades essential for assessing the efficacy of the megaprosthesis. This detailed characterization serves as the structural foundation for interpreting the functional results and safety signals, providing the necessary context for why a modular rotating-hinge system was selected as a definitive biological reset for these diverse and challenging clinical scenarios. By systematically listing age, indication, and previous surgical burden, Table 1 provides the necessary evidence to support the transition from a biological repair philosophy to a mechanical replacement strategy in the management of massive distal femoral defects.

Table 1. Detailed Patient Demographics and Clinical History

PATIENT ID	AGE	INDICATION	PRIOR SURGERIES	FOLLOW-UP (MO)	COMORBIDITIES
P1	24	GCT (Distal Femur)	0	26	None
P2	21	Osteosarcoma	0	22	None
P3	35	GCT (Distal Femur)	1	18	None
P4	52	Non-Union (DF)	3	12	DM Type II, Smoker
P5	19	Osteosarcoma	0	14	None
P6	42	GCT (Distal Femur)	1	10	None
P7	31	GCT (Proximal Tibia)	0	8	None
P8	45	Non-Union (DF)	4	4	Hypertension

Table 2 encapsulates the primary operative metrics and postoperative functional outcomes, providing the quantitative data necessary to evaluate the efficacy of the megaprosthesis as a definitive salvage strategy. The operative data reveal a distinct efficiency in the non-union cohort; specifically, Patient 4 and Patient 8 exhibited the shortest operative durations (120 and 110 minutes, respectively) and the lowest estimated blood loss (250 and 230 mL), which suggests that the mechanical reset in trauma cases can be performed with relative technical expediency compared to complex oncologic resections. Across the series, the mean Musculoskeletal Tumor Society score was 20.2 out of 30, with result grades ranging from low to excellent, reflecting the diverse functional recovery paths of the participants.

A pivotal observation within this dataset is the emergence of the Satisfaction Paradox. While Patient 4 and Patient 8 recorded lower physical functional scores—averaging a Walking Ability of 3 out of 5 due to chronic disuse atrophy—their emotional acceptance scores remained exceptionally high, with Patient 4 achieving a perfect score of 5. This contrast underscores the study's central thesis: for patients who have endured years of instability and recalcitrant non-union, the immediate restoration of mechanical stability and weight-bearing capacity is perceived as a transformative success, even if gait kinematics remain suboptimal. Conversely, the lowest MSTS score of 15 recorded for Patient 7 highlights the technical difficulties inherent in proximal tibia reconstructions, where the requirement for extensor mechanism reattachment often results in functional lag. Collectively, the data in Table 2 substantiate the megaprosthesis as a reliable bail-out that prioritizes immediate mechanical stability and psychological relief over perfect biological restoration.

Table 2. Operative and Functional Data

Correlation of surgical metrics with MSTS scores and patient emotional acceptance.

PATIENT ID	OP TIME (MIN)	BLOOD LOSS (ML)	MSTS SCORE (0-30)	EMOTIONAL (1-5)	RESULT GRADE
P1	**160**	500	24	**4**	Excellent
P2	**185**	650	22	**3**	Good
P3	**145**	400	21	**4**	Good
P4	**120**	250	19	**5**	Moderate
P5	**190**	700	18	**2**	Moderate
P6	**140**	350	22	**4**	Good
P7	**170**	550	15	**3**	Low
P8	**110**	230	18	**4**	Moderate

4. Discussion

The management of recalcitrant distal femoral non-unions represents a profound departure from standard fracture care, signaling a definitive transition from a restorative biological philosophy to a predictable mechanical one. A distal femoral non-union, particularly one that persists after multiple failed interventions, should not be viewed merely as a structural failure or a simple lack of osseous bridging; rather, it is a clinical manifestation of biological exhaustion.[11]

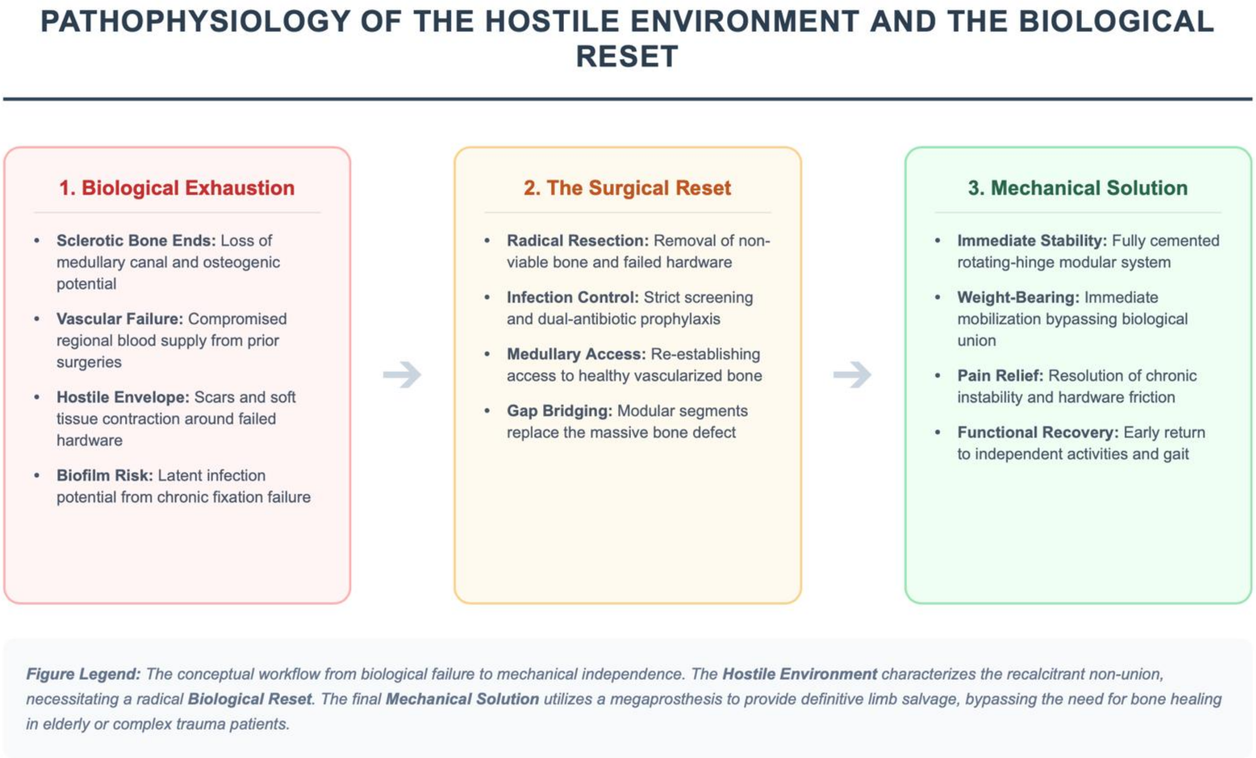

Figure 1. Pathophysiology of the hostile environment and the biological reset.

In clinical scenarios such as those observed in Patient 4 and Patient 8, the local environment is fundamentally hostile. This hostility is characterized by a constellation of pathological factors: (1) Bone Quality: The presence of sclerotic, avascular bone ends that lack the osteogenic potential required for healing; (2) Vascularity: Compromised regional blood supply resulting from previous surgical trauma, extensive scarring, and the stripping of the periosteum during repeated fixations; (3) Mechanical Integrity: Obliterated medullary canals and profound regional osteopenia that render standard internal fixation—such as plating or intramedullary nailing—technically unfeasible or likely to fail. In this hostile state, the typical regenerative pathways required for secondary bone healing are essentially deactivated. The formation of a vascularized fracture callus requires a delicate balance of stability and biology that is often absent in the multi-operated distal femur.[12] Consequently, the surgeon is often forced to choose between two disparate paths: continuing to pursue osteogenesis through high-morbidity procedures—such as distraction osteogenesis, massive autologous bone grafting, or the Masquelet technique—or conceding biological defeat and pursuing an endoprosthetic bail-out.

By electing to perform what we define as a Biological Reset, the surgical team radically alters the reconstructive strategy (Figure 1). This approach involves the resection of the entire zone of biological failure, including necrotic bone, failed hardware, and non-viable soft tissue. This radical resection effectively converts an unpredictable biological problem into a predictable mechanical challenge of implant fixation. The modular knee megaprosthesis bypasses the necrotic and avascular bone ends entirely. It achieves stable, fully cemented anchorage in healthy, well-vascularized host bone situated proximal to the original injury zone.[13] This allows for the immediate restoration of structural integrity and limb alignment without the prerequisite of biological union, enabling patients to mobilize far earlier than traditional salvage methods would allow.[14]

A compelling discovery within this pilot series is the emergence of the satisfaction paradox. This phenomenon describes a notable disparity between objective physical function scores and subjective patient satisfaction. In our comparative analysis, oncologic patients frequently demonstrated superior muscle quality and higher physical scores on the Musculoskeletal Tumor Society (MSTS) scale. Despite this, they often reported lower emotional acceptance.[15]

For the oncologic patient, the reconstruction is often perceived through the lens of profound loss—a permanent alteration to a previously healthy limb and a persistent reminder of a life-threatening malignancy.[16] In contrast, trauma patients who have endured years of chronic instability, narcotic dependence, and failed biological salvage attempts perceive the megaprosthesis as a transformative triumph of independence. For a patient who has spent years in a brace or on crutches, the immediate stability of a megaprosthesis provides a level of functional freedom that was previously unattainable. Patient 4 reported a perfect emotional acceptance score of 5 out of 5, despite achieving only a moderate physical grade. This suggests that in the context of recalcitrant non-unions, the resolution of chronic instability and the immediate return to weight-bearing are more critical drivers of patient satisfaction than the restoration of perfect gait kinematics. This paradox highlights the vital importance of incorporating patient-reported outcomes into the definition of success in complex limb salvage. While the distal femur remains the primary focus of this series, the inclusion of a proximal tibia case (Patient 7) provides critical insight into the anatomical variables that influence endoprosthetic success. Patient 7 presented with the lowest MSTS score (15 out of 30) in the entire cohort, illustrating the unique technical challenges of proximal tibial reconstruction.

In distal femur resections, the quadriceps mechanism is largely preserved, allowing for a more predictable functional recovery. However, in the proximal tibia, the extensor mechanism must be radically disrupted, and the patellar tendon must be surgically reattached to the prosthesis or an allograft-prosthesis composite. This reattachment site is a frequent source of functional failure, often resulting in an extensor lag that significantly hampers walking efficiency and increases the risk of falls. The poor functional outcome of Patient 7 underscores that while the megaprosthesis provides a structural reset, the functional result is ultimately limited by the integrity and reconstruction of the surrounding soft-tissue envelope and extensor mechanism.[17]

Safety remains the paramount concern when introducing oncologic hardware into a trauma population. While our series reports a zero percent acute infection rate, this must be viewed with clinical caution. The literature consistently suggests that non-union salvage carries a significantly higher risk of prosthetic joint infection (PJI) than primary oncology resections. This increased risk is largely attributed to: (1) Dormant Biofilms: Bacteria sequestered on previously implanted trauma hardware that may be released during the reset procedure; (2) Surgical Scarring: Multiple prior surgical scars that compromise local immune surveillance and skin integrity.[18] Our early success in avoiding infection is likely due to the rigorous adherence to the Infection Rule-Out Protocol. This involved utilizing serological markers, such as Erythrocyte Sedimentation Rate (ESR) and C-Reactive Protein (CRP), and mandatory synovial fluid aspiration prior to the mechanical reset. Furthermore, the use of dual-antibiotic-loaded cement—containing Gentamicin and Vancomycin—provided a localized antimicrobial shield against latent organisms.[19]

We must acknowledge the mechanical price of this surgical intervention. Unlike biological reconstructions, which may improve with time through bone remodeling, megaprostheses begin to degrade from the moment of implantation. In younger, active trauma patients, the rates of aseptic loosening and mechanical failure increase significantly in the five- to ten-year range. Potential failure modes include: (1) Bushing Wear: Gradual degradation of the polyethylene hinge components; (2) Aseptic Loosening: Failure of the bone-cement interface due to high torsional loads; (3) Stem Fracture: Fatigue failure of the metallic components under physiological stress. Consequently, surgeons must perform thorough preoperative counseling, ensuring patients understand that while the megaprosthesis provides an immediate bail-out, it introduces a lifelong risk of late-onset mechanical failure and secondary infection.[20]

The primary limitations of this study include the small cohort size and the relatively short-term follow-up of 14.8 months. As a pilot descriptive series, this research serves as a proof-of-concept for the biological reset philosophy but lacks the statistical power to draw definitive conclusions regarding long-term survivorship compared to other salvage methods. Additionally, the heterogeneity between the oncologic and non-oncologic groups introduces age-related confounders that may influence functional performance. Future research must prioritize the development of larger, multi-center registries dedicated to endoprosthetic use in non-oncologic indications. Such data are necessary to: (1) Define Failure Modes: Identify the precise mechanisms of failure in the trauma population; (2) Survivorship Curves: Determine the long-term durability of these constructs; (3) Decision-Making Algorithms: Establish criteria for when to abandon biological attempts in favor of a mechanical reset. Prospective studies comparing megaprosthesis to other salvage options, such as the Masquelet technique or circular fixation, would be invaluable in creating a decision-making algorithm for the management of the hostile distal femoral environment.

5. Conclusion

The modular knee megaprosthesis represents a definitive and effective salvage option for the management of recalcitrant distal femoral non-unions where biological potential has failed. By conceptualizing the procedure as a biological reset, the surgeon is empowered to convert an intractable biological failure into a predictable mechanical solution, providing immediate structural stability and limb alignment. Our findings suggest that while trauma patients may exhibit lower physical functional scores than their oncologic counterparts due to long-standing disuse atrophy, they experience profound emotional relief and high levels of satisfaction. This satisfaction paradox emphasizes that for those exhausted by multiple failed surgeries, the immediate restoration of mobility and pain relief is a primary determinant of surgical success. Nevertheless, the procedure is not without significant risks. Surgeons must remain vigilant in their adherence to strict infection screening protocols to address the latent risks of biofilm-related infection. Furthermore, patients must be counseled regarding the mechanical price of the reconstruction, specifically the long-term risk of aseptic loosening and mechanical wear. In conclusion, for the multiply-operated patient with a flail limb and exhausted biology, the megaprosthesis offers a reliable mechanical reset that can restore independence and quality of life when all other biological attempts have failed.

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