



Efficacy and complications of the induced membrane technique for immediate bone reconstruction in complex hand injuries

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Abstract

Purpose To report the radiological outcomes and complications of the Masquelet induced membrane technique (IMT) for acute bone reconstruction in complex hand injuries.

Methods We retrospectively reviewed 22 patients treated primarily by the IMT for bone defect of the phalanx and/or metacarpals bones in 26 injured digits. The median bone defect length was 17 mm (IQR 13–25). Given the severity and variability of the lesions, revision parameters focused on bone healing and postoperative complications.

Results At the median follow-up of nine months (IQR, 6–14 months), bone union was achieved in 25 digits (96%) with a median delay of three months (IQR, 2.5–3.5 months) after stage 2. Postoperative complications occurred in 11 of 26 digits requiring revision surgery in nine of 26 digits (35%). Soft tissue coverage failure and infection were the main complications. A patient underwent a late amputation through the metacarpophalangeal joint due to an uncontrolled bone infection.

Conclusions Despite a significant rate of complications, bone reconstruction using the IMT is a reliable procedure for achieving bone healing of phalanx or metacarpal bone defects in complex hand injuries.

Keywords Masquelet technique · Induced membrane · Hand injury · Bone defect

Introduction

Complex traumatic injuries of the hand involve an open fracture associated with at least one additional tissue injury (blood vessel, nerve, and musculotendinous) and a various amount of soft tissue or bone defect. The treatment of such multi-tissue injuries is always challenging, even for specialized hand trauma surgeons. Stabilization of the bone is usually the first operative step to allow a safe repair of the other tissues [1]. Bone defect is rare but makes the reconstruction

more complex. Various surgical methods have been reported in the literature to manage bone defects including one-stage bone grafting, with autograft or allograft, as well as staged reconstructions [2–5].

The induced membrane technique (IMT) is a two-stage bone reconstruction method described by Masquelet et al. [6] for treating septic non-union of the leg. The first stage involves wound debridement, bone stabilization, filling the bone loss with cement, and covering the wound if necessary. The second stage includes removing the cement and bone autografting while preserving the membrane induced by the cement. Since its introduction, the indications for the IMT have been extended to bone defects of any origin and location, including at the hand level. In the context of hand trauma, delayed bone grafting is safety when the course of soft tissues is uncertain in the first days [7, 8]. In addition, the IMT is perfectly suited for the ideal immediate multi-tissue reconstruction since it provides primary stability, allowing for early mobilization [9, 10]. Finally, the cement could theoretically limit bone contamination when flap reconstruction must be delayed. However, the studies published so far are few, small, and report varying complication rates that seem high when IMT is applied in emergency situations

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[10–14]. Thus, the value of IMT in the emergent treatment of complex hand trauma remains to be determined.

The purpose of this study was to report the outcomes of the IMT for primary bone reconstruction in complex hand injury. We hypothesized that the IMT is a reliable and safe technique for phalanx and metacarpal bone reconstruction in the acute setting.

Patients and methods

Study design, patients and data collection

After obtaining institutional review board approval of our institution, a retrospective, observational single-center study was conducted between January 1, 2006 and December 31, 2022 in a specialized hand emergency unit (Edouard Herriot hospital, Lyon, France). Complex traumatic injuries of the hand associated with bone loss are usually treated with immediate IMT to allow for finger mobilization on day one, to enable secondary bone grafting, and to protect the bone from environmental contamination in cases of delayed soft tissue reconstruction. To evaluate the pertinence of such a strategy, only the patients presenting with phalangeal or metacarpal bone defect less than 24 h old were included. Patients were excluded if they underwent surgery after the first 24 h following the trauma, or if the IMT was applied in a further stage.

Surgical protocol

The procedure was performed under locoregional anaesthesia. A tourniquet was inflated on the upper limb. The first

step consisted of a wound debridement with assessment of tissue damage. Bone reconstruction followed the principles of the IMT adapted to hand injury as described by Masquelet and Obert [11] (Figs. 1 and 2). Internal fixation with K-wire was performed in all cases during stage 1. The bone defect was filled by a polymethylmethacrylate spacer impregnated with Gentamycin (Palacos-Genta®, Heraeus Medical, Wehrheim, Germany) taking care to wrap the bone ends. Following bone stabilization, associated blood vessel, nerve and tendon injuries were repaired together with immediate or delayed soft tissue reconstruction when indicated. In cases of delayed soft-tissue coverage, negative pressure wound therapy was applied until flap transfer completion. Post-operative antibiotic therapy with amoxicillin and clavulanic acid was systematically started for five days. Stage 2 was performed after a minimum of six weeks, but the T1-T2 interval could be longer when prolonged antibiotic therapy was required or if a complication occurred between stages. During stage 2, the induced membrane was carefully opened to remove the cement. Bone fixation was either retained or replaced according to the surgeon's preference. Bone ends were refreshed, and the induced membrane filled with cancellous or cortico-cancellous bone graft harvested from the anterior iliac crest or the distal radius.

Clinical and radiological assessment

Computerized patients' records were retrieved to collect pre-operative, intra-operative, post-operative data and radiological assessment. The primary outcome was bone healing, assessed on radiographs including two orthogonal views (anteroposterior and lateral) and defined as the presence of three sections of continuous cortical bone. Secondary

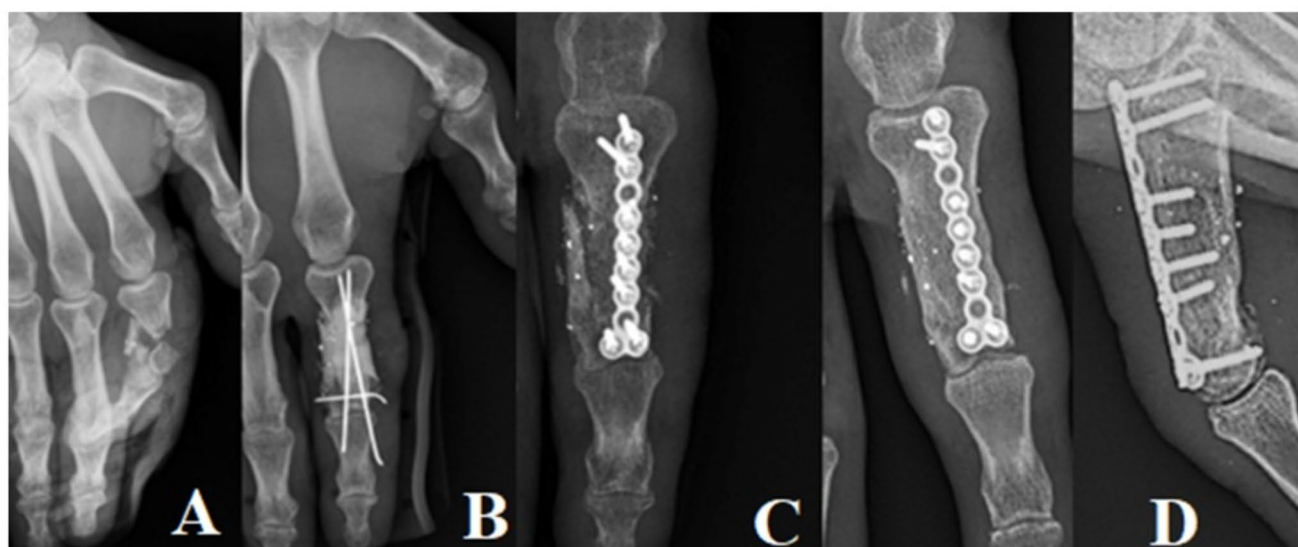


Fig. 1 Radiographs showed a complex fracture of the first phalanx with bone loss (A). First step of induced membrane technique with pins stabilization (B). Second step of the membrane induced technique with bone graft and plate/screws fixation (C). Outcome with bone healing (D)



Fig. 2 Radiographs showed a complex fracture of the three ulnar digits with bone loss and a fracture of the neck of the second metacarpal (A); corresponds to patient 6 in Table 3. First step of induced membrane technique with pins stabilization for the three ulnar digits and

plate fixation for the other fracture (B). Outcome with bone healing after simple bone graft for M5 and metacarpophalangeal arthrodesis of M4-3

outcome was the occurrence of a complication. Two physicians who were not involved in the patients' management reviewed all the data and radiographs at final follow-up. Bone healing was assessed by the two physicians independently for all patients. When they did not agree regarding bone healing, they reviewed the case together to come to an agreement.

Statistical analysis

Continuous variables are reported as medians with interquartile ranges (IQR). Categorical variables were reported as proportions. Normality and heteroskedasticity of data were assessed with the Shapiro-Wilk test and the Levene's test. The difference of the delay to consolidation according to the occurrence of complication or not was assessed with the Welch's T-test. Alpha risk was set to 5% ($\alpha=0.05$).

Results

Demographic and preoperative data

During the inclusion period, 24 patients underwent bone reconstruction of phalanx and/or metacarpals by the IMT within the first 24 h of a complex traumatic injury of the hand. Two patients were lost to follow-up, thus 22 patients

totalizing 26 injured digits were included in the study (two patients had two digits involved, one patient had three digits involved). Patients' characteristics and injury pattern are summarized in Tables 1 and 2, respectively. The injury mechanism involved power tool in 14 cases (e.g. circular saw), public road accident in eight cases, ballistic injuries in two cases and crush injuries in two cases.

Surgical data

Surgical parameters are presented in Table 3. Eight arterial lesions (including one finger devascularization), seven nerve lesions and 16 tendons lesions were addressed during stage 1. Flap reconstruction was needed in 10 digits. Six local flaps were performed immediately. Two patients with large soft-tissue defects were initially treated by negative wound pressure therapy, then underwent delayed soft tissue coverage using a pedicled groin flap (in a patient with 3 digits involved) and a posterior interosseous flap.

The stage 2 was performed after a median delay of 2.5 months (IQR, 1.5–3.5 months). Bone grafting was carried out using cancellous bone in 14 digits and an iliac cortico-cancellous graft in 11 digits. Definitive bone fixation was internal in all cases. Four digits did not require fixation due to the continuity of at least one cortical bone. Metacarpophalangeal or interphalangeal joint fusion was performed in 11 digits (Table 3).

Table 1 Patient's characteristics

Patients– number	22
Age– year, median (IQR)	52 (22–61)
Gender	
Male	20 (91)
Female	2 (9)
Dominant side injured	7 (32)
Active smokers	8 (36)
Work	
Manual	9 (41)
Retired	7 (32)
Sedentary	3 (14)
Students	2 (9)
Unemployed	1 (4)
Work-related trauma	6 (27)

Results are presented as count (%). IQR = interquartile range

Table 2 Characteristics of the complex traumatic injuries of the hand

Digit injured*	26
Thumb	7 (27)
Other fingers	19 (73)
Bone injured	
Phalanx	14 (54)
Metacarpal	7 (27)
Phalanx and metacarpal	5 (19)
Injured surface	
Dorsal	16 (61)
Lateral	9 (35)
Palmar	1 (4)
Gustilo classification	
IIIA	15
IIIB	10
IIIC	1
Bone loss	Median 17 mm (IQR 13–25)
<10 mm	4 (15)
10–20 mm	13 (50)
>20 mm	9 (35)
Articular involvement	17 (65)
Associated injuries	
Artery	8 (31)
Nerve	7 (27)
Tendinous	21 (81)
Extensor tendon	17
Flexor tendon	1
Extensor and flexor tendon	3
Skin defect	10 (38)

Results are presented as count (%). IQR = interquartile range; * Three patients had more than one finger

Table 3 Surgical parameters

	Number of procedures
Stage 1 (<i>n</i> = 26 digits)	
K-wires fixation	26
Tendon repair	11
Tendon grafting or plasty	5
Artery repair	5
Artery bypass (veinous graft)	1
Nerve repair	6
Nerve grafting	1
Flap transfer	10
Stage 2 (<i>n</i> = 25 digits)	
K-wires fixation	6
Plate or screw fixation	4
No bone fixation	4
Joint fusion	11

3 months (IQR, 2.5–3.5 months) after stage 2, and 6 months (IQR, 4.5–6.5 months) after stage 1.

Postoperative complications occurred in eight patients and 11 (42%) digits. They were dominated by partial flap necrosis and infection (Table 4). A revision surgery was required in six patients and nine digits (35%). Infectious complications occurred in the two patients treated with delayed flap reconstruction, requiring several spacer exchanges in Case 6 with three digits involved. One patient underwent a trans-metacarpophalangeal amputation due to an uncontrolled bone infection 82 days after the initial trauma (Fig. 3). This was the only case where bone healing failed. When a complication occurred, the median time to bone healing after the trauma tended to be significantly higher: 6.5 months (IQR, 5–9 months) *versus* 5.5 months (IQR, 4.5–6 months, $p=0.06$). In this small series, smoking did not seem to affect the time required for bone union.

Discussion

In this study, reconstruction of posttraumatic bone defect in the phalanx and metacarpals bones using the IMT showed a satisfactory bone healing rate of 96% of injured digits despite a complications rate of 42%. Except for one case, the complications were infection and soft tissue coverage failure.

In complex hand injury, the IMT is interesting alternative to one-stage bone reconstruction using autografts or allografts [2–4]. Indeed, the future progression of the wound can be unpredictable or uncertain. IMT allows for deferring the bone graft procedure until the optimal conditions are achieved, thereby reducing the risk of bone graft loss. Our results align with those of previously published studies [10, 12–14]. All published studies presented heterogeneous population, including delay trauma, osteomyelitis, or bone

Primary and secondary outcomes

The median follow-up period after bone grafting was nine months (IQR, 6–14 months). Bone healing occurred in 25 of the 26 digits (96%). The median delay to bone healing was

Table 4 Details of postoperative complications

Patient number - Digit	Primary soft-tissue coverage	Complications	Additional surgery	Bone healing delay after initial trauma
1 - D2	Intermetacarpal flap	Partial flap necrosis	Hueston flap at day 28; 2nd stage at day 102	202 days (100 days after 2nd stage)
3 - D4	Hueston flap	Partial flap necrosis	Cross finger flap during 2nd stage at day 52	149 days (97 days after 2nd stage)
5 - D3	Hueston flap	Partial flap necrosis	Intermetacarpal flap with cement exchange at day 39; 2nd stage at day 104	187 days (83 days after 2nd stage)
8 - D1	None	Wound dehiscence	Irrigation and debridement, cement exchange and direct closure at day 42; 2nd stage at day 85	151 days (66 days after 2nd stage)
5 - D4	None	Infection (<i>E cloacae</i>)	Amputation at day 82	-
6 - D3	NPWT, then Pedicled groin flap at day 12	Infection (<i>Methicillin Resistant S epidermidis</i>)	Cement exchange at day 88; 2nd stage at day 243	325 days (82 days after 2nd stage)
6 - D4	NPWT, then Pedicled groin flap at day 12	Infection (<i>Methicillin Resistant S epidermidis</i>)	Cement exchange at day 88; 2nd stage at day 170	278 days (108 days after 2nd stage)
6 - D5	NPWT, then Pedicled groin flap at day 12	Infection (<i>Methicillin Resistant S epidermidis</i>)	Cement exchange at day 115; 2nd stage at day 170	278 days (108 days after 2nd stage)
4 - D4	None	Wound dehiscence + infection (<i>P acnes</i>)	2nd stage at day 29: shortening and bone grafting, antibiotic therapy	108 days (79 days after 2nd stage)
7 - D1	NPWT, then Posterior interosseous flap at day 6	Delayed cutaneous healing and infection (<i>Methicillin Resistant S epidermidis</i> , <i>P acnes</i> , <i>Aspergillus</i>)	No additional surgery Delayed 2nd stage at day 134	265 days (131 days after 2nd stage)
2 - D1	None	CRPS type 1	-	250 days (63 days after 2nd stage)

Delays are counted in days after the initial trauma. CRPS Complex Regional Pain Syndrome. NPWT Negative Pressure Wound Therapy

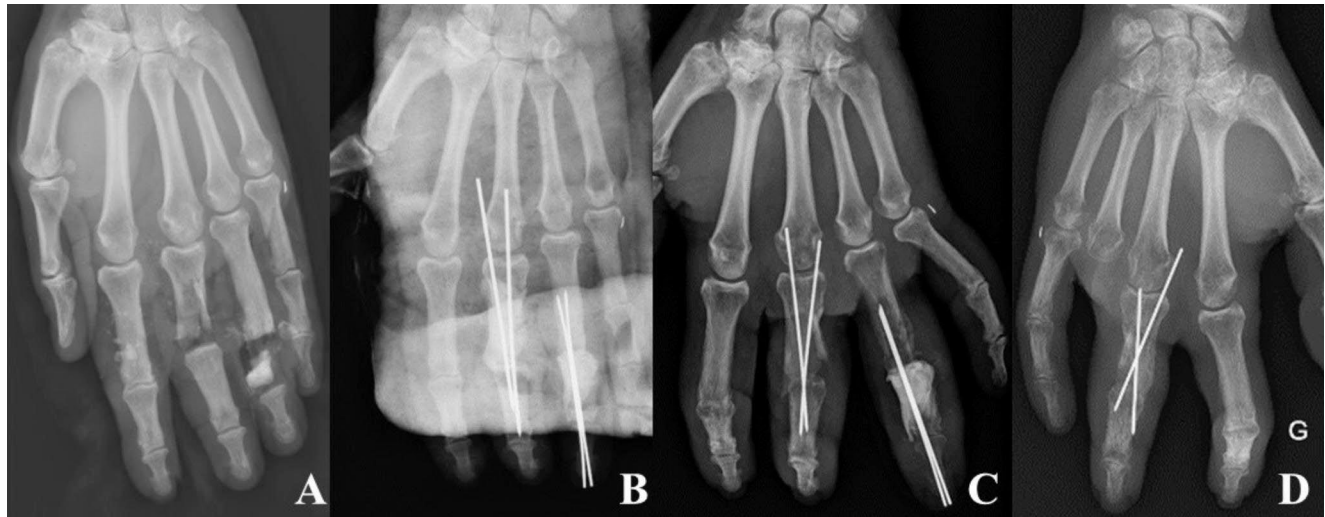


Fig. 3 Radiographs showed a complex fracture of the third and fourth digits involving the proximal interphalangeal joint with bone loss (A); corresponds to patient 5 in Table 3. First step of induced membrane technique with pins stabilization (B). Uncontrolled bone infection of

the fourth digit with osteomyelitis (C). Outcome after trans-metacarpophalangeal amputation of the fourth digit and bone grafting of the third digit

loss proximal to the metacarpals. In Table 5, we have summarized only the cases reported in the literature involving the reconstruction of traumatic bone defects in the phalanx and/or metacarpals using IMT.

The main complications were infection and soft tissue coverage failure often occurring together. While these

complications were frequently reported in the literature, they seemed to occur to a lesser degree (Table 5). However, our cohort is larger with a potentially higher injury severity. Interestingly, in their review of one-stage bone grafting, Ruta and Ozer [4] reported very few infections and emphasized the necessity of effective radical debridement

Table 5 Series reporting on phalangeal or metacarpal bones reconstruction using IMT

	Bone defects, number (injured digits)	Median defect length, mm	Complications, number (%)	Bone union, number (%)	Median time between stages, months	Median time to bone union from stage 1, months
Flamans et al. (2010)	8 (8)	At least one phalanx	3 (38)	7 (90)	3	7
Moris et al. (2016)†	18 (26)	20‡	2 (7)	16 (92)	3.5	7.5‡
Mure et al. (2011)	4 (4)	/	0 (0)	4 (100)	1.5 to 2.5	3 to 4.5
Fang et al. (2023)	12 (14)	25	0 (0)	12 (100)	2	4
Present study	22 (26)	17	7 (38)	21 (96)	3	6

† Results of this series were reported for all cases and not only for posttraumatic bone defects. ‡ Results reported in mean

and associated primary soft tissue coverage in the first stage. The relatively high rate of infection in the present series could be explained by an insufficient primary debridement or by a delayed soft-tissue coverage. Indeed, the inclusion criteria focused solely on acute complex hand injuries managed within the first 24 h. This criterion was chosen to evaluate whether IMT is reliable as part of the initial step in surgical management of these cases. Our results mostly indicate that delayed flap reconstruction carries a high risk of infection. Thus, the cement does not protect the bone from environmental contamination. Delayed soft tissue reconstruction was necessary in two cases with complex lesions requiring sophisticated flap transfer: one involving a multi-tissue injury affecting multiple digits, and another involving a crush injury with a high probability of secondary skin necrosis. In the other cases, soft tissue reconstruction was immediately performed using local flaps. Another frequent complication was secondary exposure of the spacer. Both in the hand and at the tibial level, the subcutaneous placement of the spacer results in its direct exposure with even the slightest wound dehiscence or partial flap necrosis [15]. In either case—whether it's an infection or secondary spacer exposure—it is imperative to replace the spacer and excise the already formed induced membrane to control the infection [15]. Although it is considered a complication and delays bone grafting, the spacer exchange is a precaution that is far preferable to the exposure of a primary placed bone graft. Even though there is a risk of revision for spacer exchange in the first few days, we believe that the initial implantation of a cement spacer is preferable to delayed implantation since it provides immediate stability, allowing for early mobilization [10].

In large bone defects, we used the sequential internal fixation strategy described for infected bone defect reconstruction [16]. Bone stabilization was achieved by the cement spacer combined with few K-wires during stage 1 and converted to a stable plate fixation during stage 2 with a frequent use of cortico-spongyous grafts. Our results demonstrated that this strategy is particularly adapted to the specificities of the IMT at the hand level considering the frequency of

soft tissue coverage issues and infection. In fact, this strategy offers several advantages: it is a quick, safe procedure, which is suited to complex hand injury requiring emergent multi-tissue reconstruction; the risk of bacterial adhesion is low; and the easy hardware removal facilitates iterative debridement or revision flap coverage in cases of complications [16].

Masquelet and Obert [11] initially recommended a period of six to eight weeks between the two stages on account of the peaks in growth factor levels within the membrane [17]. Various studies have subsequently reported that a longer period did not affect results [18, 19]. The results of the present study and of previously published studies suggest that the second stage may be delayed without compromising bone healing [10, 12, 20]. Bone grafting is possible after a minimum delay of six weeks but should be postponed if needed until ideal conditions have been reached: good-quality soft-tissue cover, skin of sufficient quality to allow access to the induced membrane, and no evidence of sepsis. In infected bone defect the interval between stage is also driven by the antibiotic medication duration [15, 16].

The main limitation of this study is its retrospective nature. Additionally, the absence of functional results is another limitation. However, the aim of our study was to report the efficacy of the IMT in reconstructing bone loss of the hand, which is an objective endpoint. Each case of complex hand injuries is unique, making clinical comparisons difficult. Furthermore, the limited follow-up is also a limitation, but it is common in trauma studies and was sufficient to assess bone healing and the occurrence of early complications related to the reconstruction technique. Despite these limitations, we report a significant series of the IMT for acute hand trauma and have a low rate of loss to follow-up. To the best of our knowledge, this is the largest clinical series published on the subject to date.

Conclusion

Bone reconstruction using the IMT for phalanx or metacarpal bone loss is effective in addressing complex hand injuries. Despite a significant rate of complications and revision surgeries with spacer exchange, it is a reliable technique for achieving bone healing. The IMT offers two major advantages in this setting: (1) the possibility of early finger mobilization allowed by the immediate spacer implantation, and (2) the ability to safely perform the bone graft once soft tissue issues have been avoided or treated.

Author contributions D.T. and A.W. conceived the study. D.T. was involved in protocol development, gaining ethical approval. B.M. did the patient recruitment. B.M. and D.T. did the data analysis. B.M. wrote the manuscript. L.M., V.R., A.G. and A.W. reviewed and approved the final version of the manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethical approval Ethical approval was waived by the local Ethics Committee of Edouard Herriot Hospital (Approval number 24-046; IRB No. 0013204) in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.

Consent for publication Informed consent was obtained from all individual participants included in the study.

Competing interests The authors declare that they have no competing interest.

References

1. Sabapathy SR, Del Piñal F, Boyer MI, Lee DC, Sebastin SJ, Venkatramani H. Management of a mutilated hand: the current trends. *J Hand Surg Eur Vol.* 2022;47:98–104.
2. Klifto CS, Gandhi SD, Sapienza A. Bone graft options in upper-extremity surgery. *J Hand Surg Am.* 2018;43:755–61.
3. Neuhaus V, Nagy L, Jupiter JB. Bone loss in the hand. *J Hand Surg Am.* 2013;38:1032–9.
4. Ruta D, Ozer K. Primary bone grafting in open fractures with segmental bone loss. *J Hand Surg Am.* 2014;39:779–80.
5. Woussen E, Aouzal Z, Pluvy I, et al. Hand and wrist osteo-articular bone defect: induced membrane technique indications. *Hand Surg Rehabil.* 2023;42:160–7.
6. Masquelet A, Fitoussi F, Begue T, Muller G. Reconstruction of the long bones by the induced membrane and spongy autograft. *Ann Chir Plast Esthet.* 2000;45:346–53.

7. Karger C, Kishi T, Schneider L, Fitoussi F, Masquelet A-C. Treatment of posttraumatic bone defects by the induced membrane technique. *Orthop Traumatol Surg Res.* 2012;98:97–102.
8. Raven TF, Moghaddam A, Ermisch C, et al. Use of Masquelet technique in treatment of septic and atrophic fracture nonunion. *Injury.* 2019;50:40–54.
9. Michon J, Foucher G, Merle M. Traumatismes complexes de la main: traitement tout en un temps avec mobilisation précoce. *Chirurgie.* 1977;103:956–64.
10. Moris V, Loisel F, Cheval D, et al. Functional and radiographic evaluation of the treatment of traumatic bone loss of the hand using the Masquelet technique. *Hand Surg Rehabil.* 2016;35:114–21.
11. Masquelet AC, Obert L. Induced membrane technique for bone defects in the hand and wrist. *Chir Main.* 2010;29:S221–4.
12. Flamans B, Pauchot J, Petite H, et al. Use of the induced membrane technique for the treatment of bone defects in the hand or wrist, in emergency. *Chir Main.* 2010;29:307–14.
13. Mure JP, Vimont E, Sfez J, Lagrave B. Intérêts d'une reconstruction en deux temps des petites pertes de substance osseuse selon la technique de masquelet dans le cas des traumatismes pluritissulaires de la main. *Rev Chir Orthop Traumatol.* 2011;97:S54–61.
14. Fang J, Shi R, Qi W, Zheng D, Zhu H. Feasibility evaluation of the induced membrane technique with structural autologous strip bone graft management of phalanx and metacarpal segmental defects using radiography. *BMC Musculoskelet Disord.* 2023;24:418.
15. Mathieu L, Durand M, Collombet J-M, De Rousiers A, De l'Escalopier N, Masquelet A-C. Induced membrane technique: a critical literature analysis and proposal for a failure classification scheme. *Eur J Trauma Emerg Surg.* 2021;47:1373–80.
16. Mathieu L, Tossou-Odjo L, De l'Escalopier N, et al. Induced membrane technique with sequential internal fixation: use of a reinforced spacer for reconstruction of infected bone defects. *Int Orthop.* 2020;44:1647–53.
17. Pelissier PH, Masquelet AC, Bareille R, Pelissier SM, Amedee J. Induced membranes secrete growth factors including vascular and osteoinductive factors and could stimulate bone regeneration. *J Orthop Res.* 2004;22:73–9.
18. Alford AI, Nicolaou D, Hake M, McBride-Gagyi S. Masquelet's induced membrane technique: review of current concepts and future directions. *J Orthop Res.* 2021;39:707–18.
19. Masquelet AC. Induced membrane technique: pearls and pitfalls. *J Orthop Trauma.* 2017;31:S36–8.
20. Gindraux F, Loisel F, Bourgeois M, et al. Induced membrane maintains its osteogenic properties even when the second stage of Masquelet's technique is performed later. *Eur J Trauma Emerg Surg.* 2020;46:301–12.

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