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Satisfactory results in five patients with septic clavicle nonunion using the modified Masquelet technique and structural iliac crest autograft

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Background: Indications for clavicle fracture fixation have increased dramatically over the last 20 years. Chronic surgical site infection is a particularly severe complication arising from this procedure and can induce nonunion and clinical disability. In such cases, the modified Masquelet technique using an iliac crest autograft (cancellous or tricortical) enables treatment of any bone infection as well as reconstruction of the segmental defect. The aim of this study was to analyze the clinical and radiological results of this procedure at mid-term follow-up.

Methods: In this monocentric retrospective study, patients suffering from a septic clavicle nonunion were treated with a modified Masquelet technique and reviewed at a minimum follow-up point of two years. They were clinically assessed using active range of motion, pain score (visual analog scale 0 to 10), Constant score, American Shoulder and Elbow Surgeons score, and subjective shoulder value score. Bone healing was measured using standard X-rays and CT scans.

Results: Five patients were included (mean age 49 years; range 30 to 62). *C. acnes* was involved in 80% (n = 4) of these cases. Following the first stage of treatment, the mean bone defect was 3.4 cm (range 2.6 to 6.4 cm). The second stage, performed at a minimum of six weeks (mean 7 ± 1 weeks), used an iliac crest bone autograft in all cases. At a mean follow-up of 5 ± 3 years, the mean pain score was 0.3/10 points (0 to 1), the mean Constant score was 86 points (78 to 96), the mean American Shoulder and Elbow Surgeons score was 98 ± 2%, and the subjective shoulder value score 91 ± 11%, with two “forgotten shoulders” out of five. On CT scan analysis, bone healing was achieved in 100% of cases. One plate (20%) was removed one year following the procedure due to the patient's discomfort; pain and discomfort at the iliac crest site were reported in 5/5 (100%) patients.

Conclusion: The modified Masquelet technique using an iliac crest autograft is a reliable and effective technique for treating septic nonunion of the clavicle. It both treats the bony defect and eradicates infection when conducted in association with débridement and antibiotics. In the five cases reported here, this approach had satisfactory results, both subjectively and objectively, with a very low reoperation rate despite persistent pain from iliac bone harvesting.

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A retrospective analysis of the data of patients with clavicle nonunion was performed at the Toulouse University Hospital. Shoulder evaluations and/or data were gathered. According to French law on ethics, patients were informed that their codified data would be used for the study. According to the French ethic and regulatory law (public health code), retrospective studies based on the exploitation of usual care data should not be submitted to an ethics committee, but they have to be declared or covered by reference to the methodology of the French National Commission for Informatics and Liberties (CNIL). A collection and computer processing of personal and medical data were implemented to analyze the results of the research. Toulouse University Hospital signed a commitment of compliance to the reference methodology MR-004 of the French National Commission for

Informatics and Liberties (CNIL). After evaluation and validation by the data protection officer and according to the General Data Protection Regulation*, this study after completing all the criteria, is registered in the register of retrospective study of the Toulouse University Hospital (number's register: RnIPH 2023-24) and covered by the MR-004 (CNIL number: 2206723 v 0). This study was approved by Toulouse University Hospital and confirms that the ethical requirements were totally respected in the above report.

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Fractures of the clavicle account for 2%–4% of all fractures in adults, but predominantly take place in males.^{16,17,23,26} Surgical treatment is required in 11%–47% of cases,^{16,17,23} while post-operative infection is reported in 2%–5% of those patients treated surgically.^{2,9,24} In acute situations (less than four weeks after the operation), early revision with wash-out and prolonged antibiotic therapy is recommended.²³ In chronic cases (more than four weeks after the operation), both nonunion and hardware failure can occur. *Staphylococcus aureus* and/or *Cutibacterium acnes* are often identified, with polymicrobial involvement in half of all cases.¹¹ Removal of the hardware combined with excision of the sequestrum is often necessary. This, however, leads to a bony defect that cannot result in healing.¹⁰ The Modified Masquelet technique is a well-known and effective treatment for symptomatic septic long-bone nonunion, particularly in the lower extremities.^{18,19} It is performed in a very small number of cases of septic clavicular nonunion in adults and congenital pseudarthrosis in children.^{7,8,14,15} It aims to restore the continuity of the clavicle without shortening it by more than 10%, even if the bone defect reaches several centimeters.^{20–22} Where the nonunion in question is septic, the use of antibiotics after bone resection and before bone grafting is recommended.¹⁹

The aim of the study was to analyze the mid-term clinical and radiological results of the Modified Masquelet technique with an iliac crest autograft (cancellous or tricortical) used to treat septic clavicle nonunion. We set out with the hypothesis that the Masquelet technique facilitates bone healing even when bone defects are critical and can be combined with antibiotics to treat infection.

Methods

The details of this study were comprehensively explained to the participants, each of whom consented to participating in it. Institutional review board approval was obtained for this study (RnIPH 2019-20).

Study design

Between January 2011 and December 2020, we conducted a monocentric retrospective study at Toulouse University Hospital. This study included patients who were suffering from a (1) mid-shaft or lateral clavicular nonunion (2) with a bone defect of more than 2 cm (3) associated with intraoperative positive samples, and (4) who had undergone two-stage surgery according to the Masquelet technique. They were also required to have undergone (5) a clinical and radiological follow-up of more than two years. We excluded patients who had been treated with a one-stage clavicle procedure or patients with post-traumatic neurovascular deficits.

Surgical technique

All patients were operated on under general anesthesia combined with an axillary nerve block in the “lazy beach chair” position. Cefazolin 2G was administered once intraoperative samples had been taken. During the first stage, the previous skin incision was reused for the clavicle approach. Hardware was removed first before bacteriological samples were performed using soft tissue as well as bone (minimum of five samples per patient). Care was then taken to débride soft tissues meticulously and to resect shaft extremities until normal appearance of bone was reached, with preservation of healthy tissue.^{18,19} The bridged bone defect was filled with a homogeneous polymethyl methacrylate cement spacer with antibiotics (gentamicin). The wounds were then closed, with a drain left in place for two days. The shoulder was immobilized in a sling without any physiotherapy for six weeks.

Probabilistic antibiotic therapy was immediately initiated for 21 days, targeting *C. acnes* and coagulase-negative *Staphylococcus*. Antibiotic therapy was then adapted for a total of six weeks, according to intraoperative sample analysis.

The second stage was performed at an average of 7 ± 1 weeks. Under the same operative conditions, the index approach of the clavicle was reused.^{18,19} The presence of the induced membrane was confirmed, and it was incised carefully. New bone and soft tissue samples were sent for bacteriological analysis, and an iliac autologous bone graft was substituted for the cement spacer. If the bone defect was less than 3 cm ($n = 2$), an iliac cancellous graft was placed inside the cavity without additional fixation, and the induced membrane was sutured. If the bone loss was greater than 3 cm ($n = 3$), a tricortical bone graft was impacted, and an additional screw fixation was put in place using an area of the index plate that was free of holes.¹² The index plate was not changed during the second stage of the procedure.

Antibiotic therapy was maintained for 21 days postoperatively (Linezolid, orally administered) and then adapted depending on the results of the analysis of new samples (all the samples taken were negative during the second Masquelet stage). The shoulder was immobilized in a sling for three weeks before physiotherapy commenced, consisting of pendulum exercises and pain-free active mobilization without restriction in stretching exercises and lifting heavy loads were both possible once the patient had healed.

Clinical evaluation

All patients were examined by an independent examiner (V.M.). Evaluation was performed at 45 days, three months, six months, and then annually. Pain (visual analog scale), active mobility, Constant score,¹⁰ subjective shoulder value score,¹³ and American Shoulder and Elbow Surgeons (ASES) score were assessed. At the final follow-up, patients were asked whether they were able to return to work and sport, as well as how satisfied they were in general and whether they had a possible “forgotten shoulder” (whether the shoulder felt like a normal shoulder with no further sensation of having undergone surgery).⁴

Radiological assessment

X-rays were taken immediately following the operation at 45 days, three months, six months, and then annually to assess bone healing and the absence of hardware migration, screw cut-out, or osteolysis. CT scans were performed at three and six months to more accurately measure bone healing.

Statistical analysis

Quantitative variables were analyzed using Mann-Whitney and Wilcoxon tests. Chi-square and Fisher tests were used to analyze qualitative variables. A value of $P < .05$ was considered statistically significant. Statistical analysis was performed using EasyMedStat software (version 3.23; EasyMedStat, Levallois-Perret, France).

Results

Patients

Five patients in total met all of the inclusion criteria. The epidemiological characteristics of these patients are summarized in Table I. The mean age at surgery was 49 ± 12 years. At least one to three procedures had been performed previously but had failed to achieve healing.

Table 1
Epidemiologic data, previous procedures, and antibiotics.

Patient	Sex	Age	Dominant side operated	Number of previous surgeries	Type of surgery Before Masquelet	Antibiotics after 1st stage of Masquelet	Antibiotics after 2nd stage of Masquelet	Tobacco use
1	F	59	N	1	Nonunion treatment (plate without graft, no ATBs, no samples)	Tazocillin + vancomycin + gentamicin IV: 5 days, then linezolid PO: 2 weeks, then amoxicillin PO: 3 weeks	daptomycin IV: 7 days, then amoxicillin PO: 2 weeks	Y
2	M	62	Y	3	Primary fixation (plate fixation) + 2 nonunion treatments (cancellous graft and tricortical graft with plate, no ATBs, no samples)	Tazocillin + vancomycin IV: 5 days, then linezolid PO: 4 weeks	Linezolid PO: 3 weeks	N
3	M	30	Y	2	Primary fixation (lateral plate) + nonunion treatment (iliac graft and arthroscopic endo-button fixation, no ATBs, no samples)	Tazocillin + vancomycin IV: 5 days, then linezolid PO: 4 weeks	Linezolid PO: 3 weeks	Y
4	F	52	Y	2	Primary fixation (plate fixation) + revision of fixation 3 months later (plate removal and new plate without graft, no ATBs, no samples)	levofloxacin and rifampicin PO: 15 days, then amoxicillin PO: 4 weeks	Amoxicillin PO: 4 weeks	Y
5	F	46	N	2	Primary fixation (plate fixation) + nonunion treatment (decorication, cancellous graft and plate in 1 stage, no ATBs, no samples)	linezolid PO: 15 days, then amoxicillin + rifampicin PO: 4 weeks	amoxicillin + rifampicin PO: 4 weeks	N

Y, yes; N, no; F, female; M, male; ATBs, antibiotics; IV, intravenous; PO, per os.

Bone defects and plate fixation

The average bone loss was 3.4 cm (range 2.6 to 6.4 cm).

The clavicle was fixed using a precontoured plate, either anteriorly (n = 4) or latero-superiorly with locking screws (n = 1) (Variax; Stryker, Kalamazoo, MI, USA).

Clinical results

At a mean follow-up of 59 ± 35 months, no clinical recurrence of infection was observed. Two patients had a “forgotten shoulder” (40%) (Fig. 1). One patient (20%) required plate removal due to discomfort and skin irritation at 12 months following the operation. All patients reported pain at the iliac bone harvesting site. Pain, Constant score, subjective shoulder value, and ASES had significantly improved by the final follow-up (Table II). Based on intraoperative samples at the first stage, chronically infected nonunion was confirmed in all cases, with four patients testing positive for *C. acnes* and one patient for *S. aureus* and *Coryne bacterium*.

Radiographic results

On plain X-rays, no migration of hardware was observed during the follow-up period. On CT scan, bone healing was obtained in all cases at a mean time of 3.5 ± 1.5 months (Fig. 2).

Discussion

Nonunion with chronic infection is a severe complication following Open Reduction and Internal Fixation of clavicle fracture. It raises questions regarding how to facilitate the healing of the fracture and how to eradicate the infection without reducing the length of the clavicle.²⁰⁻²² In this study, five patients were treated in a two-stage procedure as recommended by Masquelet.^{18,19} In all cases, the bone defect was both critical and over 2 cm long. The first stage involved removing the index hardware, taking bacteriological samples, performing a new fixation with a plate, filling the bone defect with cement, and administering general antibiotic therapy. At the second stage, an autologous iliac crest bone graft was placed within the induced membrane with further antibiotic therapy. We refer to the technique used as the Modified Masquelet technique because, for three patients with significant bone loss, a tricortical graft was used, whereas Masquelet’s original technique uses a cancellous graft. This technical modification removes all clavicle bone loss limits. In the mid-term follow-up, all nonunions were healed without clinical recurrence of infection. No complications occurred, and only one reoperation was required for plate removal. The mean Constant score was 85 points, subjective assessment of the shoulder was 90% of a normal shoulder, and the mean ASES was 98 points.

The treatment of infections following clavicle fractures, whether treated surgically or not, presents a therapeutic challenge.^{7,11} Functional impairment is explained by pain that can have two etiologies: active infection with an inflammatory reaction and mobility of the fracture site because of bone nonunion.¹¹ To our knowledge, no studies to date report the results of Masquelet’s induced membrane technique for treating septic nonunion of the clavicle in adults.^{18,19} This technique has been used successfully in children, as illustrated by case reports, for a short series of congenital pseudarthrosis with a bone defect ranging from 2.5 to 6 cm.^{14,15} Following pseudarthrosis resection, clavicle fixation was achieved with a Kirschner wire combined with cement. After six weeks, a posterior iliac cancellous bone graft was harvested and placed within the induced membrane, which was carefully

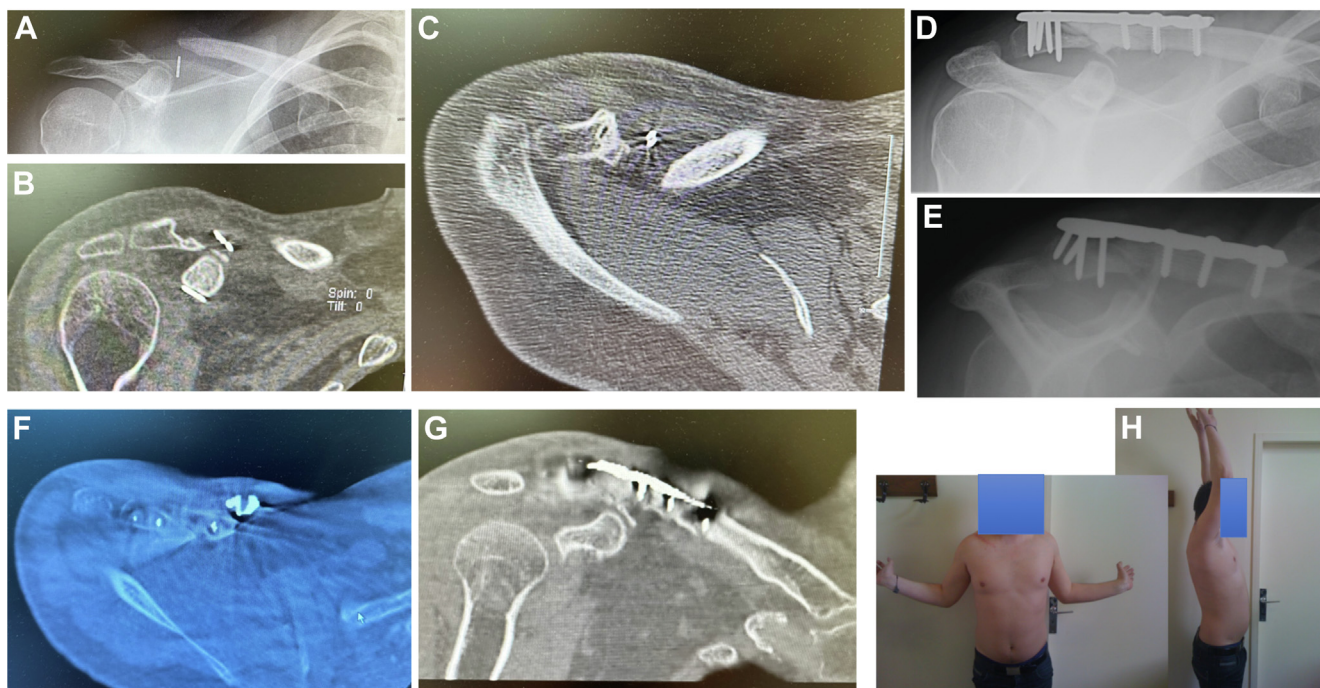


Figure 1 (A) Failed primary treatment of nonunion (endo button and iliac crest) (B, C) with 2.9 cm of bone loss and *C. acnes* sepsis in a 30-year-old patient (case 3). (D) First stage of Masquelet technique (removal of material, cement, and lateral superior plate with locking screws); (E) Second stage of Masquelet with iliac cancellous bone graft without (F, G) CT scan showing healing fracture at three months with a satisfactory clinical result (H).

Table II

Clinical results.

	Preoperative	Postoperative	P value
VAS (points)	7 ± 1	1.4 ± 1.5	.01
AAE (degrees)	132 ± 11	168 ± 10	.02
AER (degrees)	36 ± 5	66 ± 10	.02
AIR (points)	6 ± 0.5	10	.004
Constant score (points)	45 ± 5	85 ± 12	.01
SSV score (%)	42 ± 11	91 ± 11	.01
ASES score total	52 ± 17	98 ± 2	.02

VAS, visual analog scale; AAE, active anterior elevation; AER, active external rotation; AIR, active internal rotation; SSV, subjective shoulder value; ASES, American Shoulder and Elbow Surgeons.

preserved. In adults, a stable fixation tends to be recommended, meaning that a plate remains the most appropriate option for the clavicle. As Masquelet initially described,¹⁸ external fixation would have been an alternative in our series. An external fixator on the clavicle is, however, recommended where there is a poor-quality cutaneous environment; it may be uncomfortable for the patient and requires local care twice each day.⁵

Except in one instance, anatomic plates were placed at the anterior part of the clavicle despite a well-known lower rigidity than in superior position.³ Indeed, thanks to this fixation, we could easily support the shaft with bicortical screws in an area free of holes while preserving access to the cement for the second stage. However, a superior plate was used in one case because the nonunion site was too lateral to guarantee a stable fixation using an anterior plate. In this particular case, no plate had been used at the index procedure, allowing us to place the plate at our convenience. Fleur Ae van der Burg et al reported a rate of 100% bone healing in a short series (five patients) treated for clavicle nonunion with bone defects ranging from 3 to 6 cm.²⁵ They recommend reconstructing the damaged area using a cortico-cancellous bone graft and two plates at 90°. Given the combined effects of the bulkiness of the

hardware and the condition of the patients' skin, however, the patients were considered to be at risk when it came to wound healing in our experience.¹²

Duncan et al's findings¹¹ highlight the difficulty of treating septic nonunion with or without previous fixation. They reported a series of six cases with a success rate of only 33%.¹¹ No reconstructive techniques were used in this series. The advantages of Masquelet's induced membrane technique for treating clavicle nonunion are twofold: firstly, it enables us to débride soft tissue and resect chronically infected bone; secondly, it allows us to reconstitute the clavicular length with free graft, even where critical bone loss has occurred, thanks to a better vascularized environment conducive to bone healing.^{7,8,18} The ideal time for this second stage was reported to be between four and eight weeks following the operation.¹⁸ In agreement with the infectiologists, this allowed us to start a six-week process of probabilistic and then curative antibiotic therapy. At the second stage, antibiotic therapy was maintained for a minimum of three weeks, reaching a total time of more than two months. This second perspective based on new intraoperative samples would theoretically confirm the efficiency of the first line of antibiotics.

Calori et al⁸ used the cancellous femoral bone (Reaming-irrigating-aspirating technique) augmented with mesenchymal stem cell MSCs and bone morphogenetic protein-7 to reconstruct a bone defect of more than 3 cm in a case of atrophic nonunion. The advantage of the Modified Masquelet technique is that no osteoconductive, osteoinductive, or osteogenic materials need to be added, making this technique less expensive. It also avoids complex vascularized bone graft procedures, reducing operating time, bleeding, and the length of hospital stay.¹ Moreover, it requires an iliac crest autologous bone harvest, which is associated with non-negligible morbidity. Clinical assessment in our series confirmed significant pain from the iliac crest with short-term impairment of the lower limb, which is in line with the findings reported in the literature.⁵

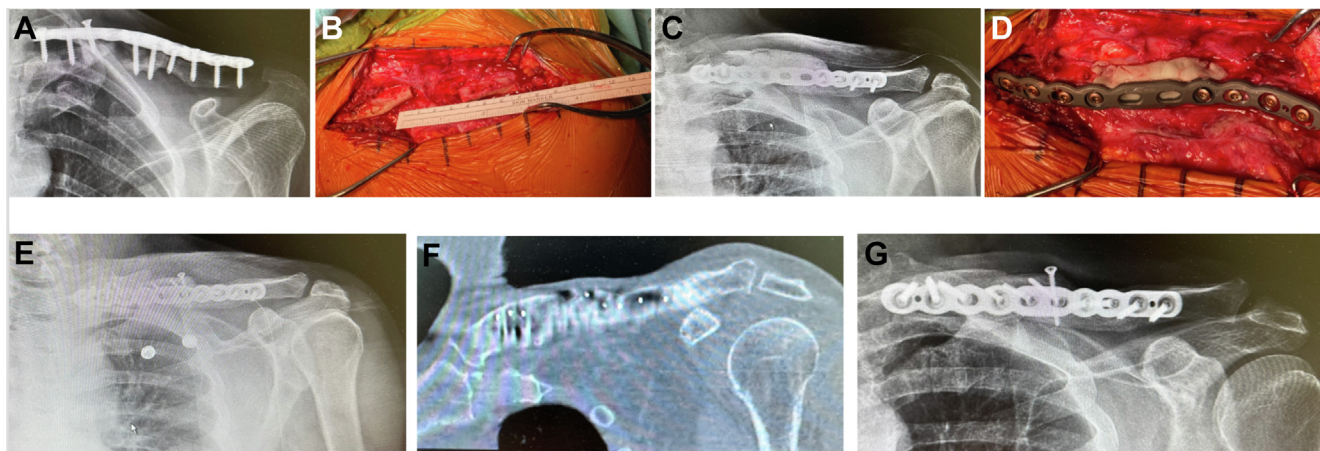


Figure 2 (A) 50-year-old woman with failed clavicle fixation (hardware failure and *C. acnes* sepsis), (B) associated with a 3.7 cm bone defect. (C, D) Hardware removed, cement, and anterior plate placed. (E) After seven weeks, second stage for placement of a tricortical bone graft fixed additional screw within the induced membrane cavity. (F) CT scan and (G) radiograph at four months after the operation show bone healing.

Our study has several limitations. First of all, it is a retrospective, monocentric study with mid-term follow-up in a small number of patients. Moreover, we modified the original induced membrane technique by using a cortico-cancellous (and not pure cancellous) bone graft for the largest bone defect. Our cut-off of 3 cm was also defined arbitrarily. In addition, we did not compare this technique with alternative procedures. Notwithstanding these limitations, however, this is the first study to report the Modified Masquelet technique in an uncommon but challenging pathology. This strategy has already been validated in chronic infections of the long bone. But our study's originality lies in the anatomical and biomechanical condition of the clavicle. Finally, clinical evaluation was performed at an average of close to five years, and bone healing was confirmed using CT scans, which are more accurate than X-rays.

Conclusion

The modified Masquelet technique using an iliac crest autograft is a reliable and effective method for treating septic nonunion of the clavicle. It treats the bony defect and eradicates infection by being conducted in association with débridement and antibiotics. In the five cases reported here, this approach had satisfactory results, both subjectively and objectively, with a very low reoperation rate despite persistent pain from iliac bone harvesting.

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