

■ UPPER LIMB

Allograft-prosthesis composite reconstruction for the management of failed elbow replacement with massive structural bone loss

R. Amirfeyz,
D. Stanley

From Upper Limb Unit, Northern General Hospital, Sheffield, United Kingdom

A MEDIUM-TERM FOLLOW-UP

We studied, ten patients (11 elbows) who had undergone 14 allograft-prosthesis composite reconstructions following failure of a previous total elbow replacement with massive structural bone loss. There were nine women and one man with a mean age of 64 years (40 to 84), who were reviewed at a mean of 75 months (24 to 213). One patient developed a deep infection after 26 months and had the allograft-prosthesis composite removed, and two patients had mild pain. The median flexion-extension arc was 100° (95% confidence interval (CI) 76° to 124°). With the exception of the patient who had the infected failure, all the patients could use their elbows comfortably without splints or braces for activities of daily living. The mean Mayo Elbow Performance Index improved from 9.5 (95% CI 4.4 to 14.7) pre-operatively to 74 (95% CI 62.4 to 84.9) at final review.

Radiologically, the rate of partial resorption was similar in the humeral and ulnar allografts (three of six and four of eight, respectively; $p > 0.999$). The patterns of resorption, however, were different. Union at the host-bone-allograft junction was also different between the humeral and ulnar allografts (one of six and seven of eight showing union, respectively; $p = 0.03$).

At medium-term follow-up, allograft-prosthesis composite reconstruction appears to be a useful salvage technique for failed elbow replacements with massive bone loss. The effects of allograft resorption and host-bone-allograft junctional union on the longevity of allograft-prosthesis composite reconstruction, however, remain unknown, and it is our view that these patients should remain under long-term regular review.

Revision total elbow replacement in the presence of massive bone deficiency is difficult, in part due to the osseous pathoanatomy but also the state of the surrounding soft tissues, which are frequently of poor quality. In addition, the neurovascular structures are often trapped in scar tissue, already compromised and difficult to identify.

Treatment options that have been advocated to salvage this situation have included the use of custom-made implants with or without strut grafts,^{1,2} hemi- and whole-joint allografts^{3,4} and allograft-prosthesis composites.^{5,6} We have limited experience of custom-made implants, but acknowledge that elsewhere they have been found useful for these difficult reconstructions.² The disadvantage of the technique is that the prostheses are expensive, the manufacturing process time-consuming, and if intra-operative adjustment is required to facilitate introduction of the components, compromised bone is further sacrificed.²

Urbaniak and Black³ pioneered the use of hemi- and total allograft joint replacements to reconstruct the elbow under these circumstances. Although the early results were encouraging, longer-term follow-up revealed significant complications⁴ and this technique now has limited applicability. More recently, allograft-prosthesis composite (APC) reconstruction has been proposed as an alternative option with improved outcomes.^{5,6}

This study reports our experience since 1993 of this technique for the salvage of the failed elbow replacement. In particular we report the functional and radiological outcomes of patients with massive structural bone loss.

Patients and Methods

Between January 1993 and October 2010 a total of 12 patients underwent APC reconstruction of the elbow for massive humeral, ulnar or combined bone loss at our unit. Staged bilateral surgery was performed in one

■ R. Amirfeyz, MD, MSc, FRCS(Tr & Orth), Consultant Hand and Elbow Surgeon Bristol Royal Infirmary, Department of Orthopaedics, Upper Maudlin Street, Bristol BS2 8HW, UK.

■ D. Stanley, MBBS, FRCS, Consultant Shoulder and Elbow Surgeon Northern General Hospital, Department of Orthopaedics, Herries Road, Sheffield S5 7AU, UK.

Correspondence should be sent to Mr R. Amirfeyz; email: rouin.amirfeyz@uhbristol.nhs.uk

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Table I. Summary of the data for the patients

Patient	Gender	Follow-up (months)	Age at operation	Side	Diagnosis*	Allograft type	Union	Resorption	Complication	MEPI (pre/post) [†]	Extension-flexion	Triceps strength MRC [‡] grade	Failure
1	F	213	66	Left	RA	Ulna	Yes	Partial	None	35/85	30 to 130	V	No
2	F	66	84	Left	OA	Humerus	No	Complete	Triceps deficiency, pistoning	10/80	10 to 130	II	No
3	F	108	69	Left	RA	Ulna	Yes	None	Pre-op radial nerve palsy	35/65	0 to 100	III	No
4 [§]	F	59	58	Right	RA	Humerus & ulna	Yes for ulna	None	None	5/75	0 to 90	IV	No
		30	59	Left		Humerus	No for humeri			5/75	10 to 40	IV	
5	F	71	67	Right	RA	Ulna	Yes	Partial	Radial neck impingement	10/65	35 to 90	III	No
6	F	30	68	Right	RA	Humerus & ulna	No for humerus, yes for ulna	Complete for humerus, none for ulna	Temporary ulnar neuropraxia	10/90	0 to 110	V	No
7	F	25	65	Right	RA	Ulna	No	Partial	Pre-op ulnar nerve palsy	5/75	0 to 110	IV	No
8	F	26	64	Left	RA	Ulna	Yes	Complete	Apprehension & instability	5/25	0 to 50	III	Infected failure
9	F	106	63	Right	RA	Humerus & ulna	Yes for both	None for both	Shoulder pain due to proximal migration of cement mantle	10/80	0 to 120	V	No
10	M	81	40	Left	PTA	Humerus	No	Complete	Weak triceps	5/100	0 to 130	II	No

* RA, rheumatoid arthritis; OA, osteoarthritis; PTA, post-traumatic arthritis

† MEPI, Mayo Elbow Performance Index; pre, pre-operative; post, post-operative

‡ MRC, Medical Research Council

§ patient deceased

patient (case 4). In total, 16 APCs were performed in 13 elbows. The two most recent patients, both of whom underwent humeral APCs, were excluded as the follow-up was too short (one and two months, respectively) to allow meaningful analysis. This left a cohort of ten patients (11 elbows) with three humeral, five ulnar and three humeral and ulnar APCs (Table I). At the time of review the patient (case 4) who had undergone bilateral surgery had died from unrelated causes (at 59 months and 30 months after the operations on the right and left elbows, respectively). However, detailed follow-up data (2.5 and 5 years from each index operation) allowed the patient to be included in the study.

There were nine women and one man, with a mean age at the time of surgery of 64 years (40 to 84). Five right and six left elbow reconstructions were performed. The underlying primary pathology is summarised in Table I.

At referral all patients had undergone a minimum of three previous operations, with the median being of three (95% confidence interval (CI) 1.6 to 4.4). In two patients (cases 2 and 10) more than ten attempts at reconstruction had been made. A free flap had been undertaken in one patient (case 2) to cover her wound, but unfortunately this had failed (Fig. 1). One patient (case 3) had a radial nerve palsy for which tendon transfers had been performed, and another (case 7) had a pre-existing ulnar nerve palsy, which remained permanently. In two other patients (cases 2 and 5) the triceps attachment had failed.

Surgical management. Following a careful clinical examination all patients underwent radiological and haematological assessment. This included a full blood count, ESR and CRP estimation. If there was a discharging sinus (three patients) samples were sent for microscopy, culture and sensitivity, and the joint was aspirated and the sample analysed for



Fig. 1

A photograph of a failed flap and a custom-made prosthesis in a catastrophic failure of a previous total elbow reconstruction (case 2).

infection. Prior to this investigation any antibiotics that the patient had been receiving were stopped for six weeks in order to obtain a pure culture of organisms within the joint, in accordance with standard institutional protocol.

The reconstructions were performed in two stages (Fig. 2). At the first stage all of the necrotic, non-viable macroscopically infected tissues, metalwork and bone cement were removed. A minimum of five deep-tissue samples were taken and sent for microscopy, culture and sensitivity. The wound was then thoroughly irrigated with aqueous chlorhexidine solution, after which gentamicin (1 g)-impregnated cement rods and beads were prepared in the operating theatre and inserted into the joint cavity. Additional antibiotic was added to the cement depending on the sensitivity of organisms identified from the pre-operative aspiration. If the pre-operative cultures failed to identify evidence of infection, 1 g of vancomycin was added to each pack of gentamicin-impregnated cement prior to preparation of the rods and beads. The wound was then closed and the elbow protected in an above-elbow backslab until the second-stage operation was performed. This was not undertaken until the elbow had been quiescent for a minimum of three months and all blood markers had returned to normal, or in the rheumatoid patients, their usual baseline values. If an organism was identified the patient was kept on intravenous antibiotics for six weeks (based on culture sensitivity). Cefuroxime 1.5 g intravenously was standard if no organism was identified. Otherwise, antibiotics were stopped when a negative culture was obtained.

At the second-stage procedure the previous incision was used and a posterior approach made to the elbow.⁷ The ulnar and radial nerves were identified and protected. The antibiotic-impregnated cement rods and beads were removed and the joint cavity further debrided. The allografts were of bulk type, frozen at -70°C and irradiated. The extent of bone loss was measured and an allograft

prepared to fit the defect. The elbow prosthesis was cemented into the allograft outside the patient, and then the APC was cemented into the host bone.

In our unit the technique of joining the APC to the host bone has evolved over time. Initially a step-cut was made on both the APC and the host bone. The two were interlocked and the fixation supplemented with cerclage wires (Fig. 3). At the end of the procedure the extensor mechanism was repaired to the olecranon/allograft using non-absorbable stitches.⁷ Reconstructions were performed using one Stanmore (Biomet UK Ltd, Swindon, United Kingdom), one Souter-Strathclyde (Stryker Howmedica Osteonic, Limerick, Ireland) and nine Coonrad-Morrey (Zimmer, Warsaw, Indiana) replacements.

Post-operatively the elbow was supported in an above-elbow plaster backslab until the wound had healed. Free active mobilisation was then permitted. Intravenous antibiotic treatment was stopped once the wound was dry and healing (usually three to five days).

The patients were reviewed at two, six and 12 weeks, six months, one year, and yearly thereafter. This involved an assessment of pain, range of movement, sensation of instability, triceps strength according to the MRC scale,⁸ activities of daily living and nerve dysfunction. Evaluation also included the Mayo Elbow Performance Index (MEPI),⁹ which has four domains: pain, stability, activities of daily living and movement.

Anteroposterior and lateral radiographs were assessed independently by the authors (RA, DS) for evidence of implant loosening, union at the allograft-host bone junction (as defined by cortical bone connecting the host and allograft bones together) and allograft resorption. Any discrepancies were discussed and a consensus reached. If resorption was observed, it was classified on the basis of the percentage of the total allograft considering the two orthogonal radiographic views. Union was also quantified based on the percentage of the circumference of the allograft-host bone junction adjudged to be united. The adequacy of cementing and subsequent progressive loosening was recorded based on a previously published method.¹⁰

Statistical analysis. The Kolmogorov-Smirnov test was used to assess whether the data were normally distributed. Chi-squared analysis of contingency tables, Fisher's exact test, the Mann-Whitney U test, Kaplan-Meier survival analysis and log-rank (Mantel-Cox) test were used where necessary. SPSS version 13 software package (SPSS Inc., Chicago, Illinois) was used for the analysis. Where multiple comparisons were performed Bonferroni correction was made to the level of significance, which was defined at 0.05.

Results

There were ten patients with 11 elbow replacements comprising eight ulnar and six humeral APCs with a mean follow-up of 75 months (25 to 213).

Apart from one case of coagulase-negative *Staphylococcus aureus* (case 6), the remaining initial aspirations



Fig. 2a

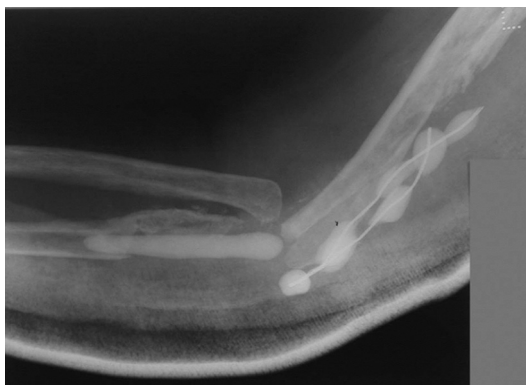


Fig. 2b

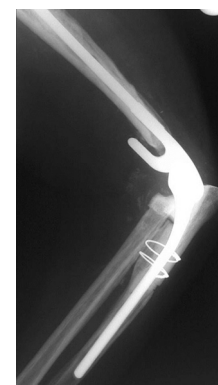


Fig. 2c

Radiographs of a woman aged 70 years at referral undergoing staged management of bone deficiency, showing a) the elbow at the time of referral, b) after radical debridement and insertion of antibiotic-impregnated beads and rods, and c) at 108 months showing the reconstructed joint with ulnar allograft.



Fig. 3a

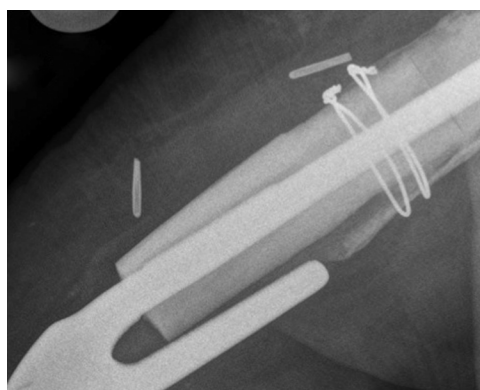


Fig. 3b



Fig. 3c

Lateral radiographs of the humeral step-cut technique of allograft-host attachment with cerclage wires (a), telescoping of the allograft prosthesis composite into the host bone (b) and the host bone onto the allograft composite component (c).

were negative for organisms both on microscopy and on short- and long-term cultures.

Clinical results. Pain/instability. Three patients complained of pain during follow-up. Patient 5 had mild pain at the lateral side of the elbow that appeared on clinical and radiological evaluation to be due to radial neck impingement. She underwent further trimming of the radial neck, with resolution of her symptoms. She has remained pain free. Patient 9 complained of mild shoulder pain, exacerbated by abduction, but with no pain at the elbow. Radiographs confirmed proximal migration of the cement mantle with extravasation from a proximal breach in the humeral cortex. She was offered an operation to remove the cement but declined, as she felt her symptoms were not sufficiently distressing. Patient 8 developed a discharging sinus 26 months after her operation due to infection, with a sensation of painful instability. Clinical and radiological assessment revealed APC failure with implant loosening, and the implant was removed. At final follow-up she has a flail arm, but has declined further surgery.

Range of movement. The final range of movement is summarised in Table I. Pre-operatively all patients had a flail elbow with no functionally useful movement. Post-operatively the range of movement achieved was maintained throughout the follow-up period.

Activities of daily living. All but patient 8 could use the operated elbow for lifting light objects without the use of a brace or support.

The mean MEPI improved from 9.5 (95% CI 4.4 to 14.7) pre-operatively to 73.6 (95% CI 62.4 to 84.9) ($p < 0.0001$, paired t -test) (Table I).

Triceps function. This was evaluated in all patients (Table I). Disruption was defined as an extensor mechanism strength of grade II or less on the MRC scale. Of the 11 APCs performed, nine had some active extension against gravity, but in two (cases 2 and 10) this was not possible, indicating disruption of the extensor mechanism. The mean strength of the extensor mechanism improved from II (I to III) pre-operatively to IV (II to IV).



Fig. 4

Follow-up lateral radiograph of an ulnar allograft-prosthesis construct at nine years. A sclerotic line is seen at the tip of the long ulnar stem, which was non-progressive. The patient was asymptomatic.

Nerve injury. At referral one patient (case 3) had an unresolved radial nerve palsy for which she had undergone tendon transfers. Patient 7 presented with an ulnar nerve palsy; the nerve was found intra-operatively to be divided at the level of the cubital tunnel and trapped in scar tissue. Only one patient (case 6) developed neurological problems following APC reconstruction which consisted of a neuropraxia of the ulnar nerve, which had recovered fully by three months after the operation.

Clinical failure of APC. Patient 8 had a failed APC that required removal due to infection 26 months after the index procedure. This patient had rheumatoid arthritis and was on steroids and methotrexate. Clinically, all other APCs had survived at the time of review.

Implant failure. Apart from patient 8, who had the implant removed because of infection, we encountered no mechanical problems including wear of the bushings, failure of the hinge mechanism, dissociation or stem failure.

Radiological results. Implant loosening. Loosening due to infection and resulting in removal of the APC occurred in one patient (case 8). The lateral radiograph of a second patient (case 2) taken nine years after the reconstruction suggested 'pistoning' of the ulnar component (Fig. 4).¹¹ However, this patient was asymptomatic and a review of the earlier radiographs showed neither progressive radiolucent lines nor evidence of anterior impingement. No other patient had progressive lucency at the cement-bone interface. All the patients had adequate cementing according to the criteria of Schneeberger et al.¹⁰

Union. In each case all radiographs were reviewed in order to assess and quantify the presence of union at the allograft-host bone junction. Two orthogonal views were assessed in each time interval to ensure a 'partial union' was not missed. The results were dichotomised for the statistical

analysis, and even a partial union (provided that both cortices were breached) was counted as positive. Although on the ulnar side seven out of eight APCs showed positive union, only one out of six humeral APCs showed union. The difference was statistically significant $p = 0.03$ (Fisher's exact test).

Allograft resorption. On the ulnar side, in four out of eight APCs resorption was observed. Three occurred proximally, either at the olecranon or the medial proximal cortex. In total, each involved less than a quarter of the allograft. In the fourth (case 8) there was a complete resorption due to infection.

On the humeral side, three out of six APCs showed resorption. The pattern on the humeral side was different from that on the ulnar side. All three showed complete resorption (Fig. 5). These occurred over a six-month period at least three years after APC insertion. No clinical evidence of infection was noted and all three patients were asymptomatic.

With regard to the number of sites of resorption, no statistically significant difference existed between the ulnar and humeral APCs (four *versus* three, respectively; Fisher's exact test, $p > 0.999$).

A trend of later resorption was observed on the ulnar side in comparison with the humeral APCs, although this was not statistically significant (mean 83.7 (60 to 90) *versus* 62.2 (50 to 70) months, $p = 0.7$, *t*-test).

Of those with resorption, three had evidence of union and four of nonunion. In the radiographs with no observed resorption these figures were five and two, respectively. The effect of union on resorption was not statistically significant (Fisher's exact test, $p = 0.59$).

The only variable of importance with regard to resorption was the number of previous operations (median 3 (95% CI 2.8 to 3.2) *versus* 5.3 (95% CI 3.1 to 7.5), two-tailed Mann-Whitney test, $p = 0.004$). Other parameters were not statistically significant (age: median 62 years (95% CI 56.7 to 67.3) *versus* 64.7 years (95% CI 55.3 to 74.1), Mann-Whitney U test, $p = 0.34$; duration of follow-up: median 37.4 months (95% CI 0.7 to 74.1) *versus* 47.4 (95% CI 0 to 95.4), Mann-Whitney U test, $p = 0.57$; and final flexion-extension arc achieved: median 85° (95% CI 47 to 123) *versus* 101.2° (95% CI 68.7 to 133.7), Mann-Whitney U test, $p = 0.38$). As multiple comparisons were performed, the Bonferroni correction was done to define the level of significance.

Using any degree of resorption as a mark of failure, the log-rank (Mantel-Cox) test failed to show any statistically significant difference in the survival rates of humeral and ulnar APCs ($p = 0.85$) but it is acknowledged the numbers studied are small.

Discussion

Management of a failed elbow replacement requires consideration of any deficiency in the bone and soft tissues, as well as the possible presence of infection. Problems may be



Fig. 5a



Fig. 5b

Radiographs showing a) typical ulnar resorption involving the proximal part, including the olecranon, and b) a typical humeral resorption pattern with complete loss of allograft.

encountered in achieving good soft-tissue cover, secure reattachment of the triceps mechanism and protection of the major nerves. It is worth considering whether the hand is insensate with poor function, which prevents even limited activities of daily living. If this situation applied then complex reconstruction of the elbow by any means is inappropriate.

Custom-made implants were originally designed for use in orthopaedic oncology surgery, and when first used for non-oncological indications had a high rate of failure¹ but subsequently more encouraging results have been published.²

An allograft is indicated for massive bone loss^{5,12} and its use at the elbow was first reported by Urbaniak and Black.³ Although they showed acceptable early results, degenerative change within the joint was noted by two years. A more recent study of allograft joint replacement reported a high rate of complications, including nerve palsies, infection, instability, resorption and failure of graft incorporation.⁴ As a result, this technique has limited application, for example in a young patient who is not a candidate for elbow replacement.

Allograft-prosthesis composites (APCs), however, have been shown to be useful in hip joint reconstruction in the presence of massive bone deficiency.¹² The use of APC reconstruction in revision elbow surgery has only been reported in two papers. The Mayo Clinic experience of 13 elbows followed up for a mean of 42 months showed recurrence of infection needing allograft removal in two cases. In a third case the allograft was removed because of a fracture. In another two cases there was a recurrence of infection, which was controlled by debridement with preservation of the APC at the time of follow-up.⁵

The second paper, comprising work from centres in Florida and Philadelphia in the United States,⁶ reported on ten patients (14 APCs) with a mean follow-up of 6.5 years (minimum of two years). One patient suffered recurrent infections and required multiple revision operations, including a further allograft. The infection was never eradicated and the patient remained on long-term suppressant antibiotic therapy. A second patient had an acute dissociation of the allograft-host bone junction post-operatively and underwent further surgery with plate fixation. A third patient sustained a fracture of the ulnar allograft and required revision of the APC.

Our experience of this salvage technique is encouraging. We had only one recurrence of infection and one post-operative ulnar nerve neuropraxia. Pain was well controlled and the final range of movement acceptable. With the exception of the patient in whom the APC was removed for infection, all patients were able to use their elbows for activities of daily living. However, we have observed a number with signs of allograft resorption, the clinical significance of which has not been established by our study but which may, of course, indicate impending failure.

Our fixation technique has evolved over time. All patients in this series had step cuts to secure the allograft to host with cerclage wire. More recently we have favoured telescoping the APC into the host bone if ballooning of the host bone is encountered. Otherwise, a wider allograft is chosen such as the proximal humeral shaft, which allows telescoping of the host bone inside the allograft. This creates a space between the APC cortex and the host bone, allowing bone graft or bone morphogenetic protein supplementation to encourage union. We also feel that this is likely to provide a stronger construct between the APC and the patient's bone than our previous step-cut technique.

To our knowledge the detailed radiological appearances following APC reconstruction and the effect of union on the final outcome have not been previously discussed. It is widely believed that union is essential for graft incorporation and survival of the allograft. In our series union at the allograft-host junction did not seem to affect the final outcome, or even the resorption rate of the allografts.

The observed radiological outcome of humeral and ulnar allografts appears to be completely different. On the humeral side, five out of six cases failed to unite, whereas on the ulnar side union occurred in seven out of eight reconstructions. This is in contrast to the findings of Renfree et al,⁶ where union was noted on the humeral side in all cases and in 57% on the ulnar side. This difference may be because they used a 3.5 mm dynamic compression plate at the allograft-host junction. We have avoided the use of plates to secure the allograft to the host bone, as we believe the application of a load-bearing implant at the junction increases the likelihood of allograft resorption. Renfree et al,⁶ however, reported a similar resorption rate to ours on the humeral side, despite the fact that they also observed union in all cases.

Although we observed a difference in union between the humeral and the ulnar allografts, there was no difference in the resorption rate between the two bones, and similarly no difference in survival. The resorption patterns were, however, different. On the humeral side we most frequently observed complete resorption, whereas on the ulnar side it was always limited to the dorsal cortex of the proximal part of the ulnar allograft. Despite not being statistically significant, resorption was noted earlier in the humeral than in the ulnar allografts (mean of 84 months *versus* 62 months). The reason for these differences is unclear, but may be related to the greater musculotendinous attachments around the distal humerus compared with the proximal ulna. This is associated with an increased blood supply around the distal humerus which may lead to earlier and more marked bone resorption. Indeed, a detailed previous anatomical study showed a more abundant blood supply to the distal humerus than to the proximal ulna.¹³ However, we have no scientific evidence to support this view. One might equally argue that scar formation due to multiple previous operations would reduce the blood supply. Whatever the reason, it warrants further investigation to try to establish the aetiology. Another explanation for resorption could be a subclinical indolent infection, but this does not explain the difference in the pattern of resorption observed.

The number of previous operations also seems to affect the resorption rate. Our study has shown that patients having had more than five previous operations were at a much higher risk of resorption than those with only three previous procedures. Such patients might have an increased blood supply to the elbow joint, which could explain the observed difference. The length of follow-up, age and range of movement do not appear to predict resorption, and implant loosening is unaffected by all these variables.

Overall, our results are encouraging. However, it is important to emphasise that this technique is by no means a first line of treatment for implant failure, as the long-term results remain unknown. We would strongly recommend that any patient undergoing this type of salvage procedure remain under indefinite review.

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