Intraoperative ‘space suits’ do not reduce periprosthetic joint infections in shoulder arthroplasty

a registry study of 16,000 primary arthroplasties

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Aims

Body exhaust suits or surgical helmet systems (colloquially, ‘space suits’) are frequently used in many forms of arthroplasty, with the aim of providing personal protection to surgeons and, perhaps, reducing periprosthetic joint infections, although this has not consistently been borne out in systematic reviews and registry studies. To date, no large-scale study has investigated whether this is applicable to shoulder arthroplasty. We used the New Zealand Joint Registry to assess whether the use of surgical helmet systems was associated with lower all-cause revision or revision for deep infection in primary shoulder arthroplasties.

Methods

We analyzed 16,000 shoulder arthroplasties (hemiarthroplasties, anatomical, and reverse geometry prostheses) recorded on the New Zealand Joint Registry from its inception in 2000 to the present day. We assessed patient factors including age, BMI, sex, and American Society of Anesthesiologists (ASA) grade, as well as whether or not the operation took place in a laminar flow operating theatre.

Results

A total of 2,728 operations (17%) took place using surgical helmet systems. Patient cohorts were broadly similar in terms of indication for surgery (osteoarthritis, rheumatoid arthritis, fractures) and medical comorbidities (age and sex). There were 842 revisions (5% of cases) with just 98 for deep infection (0.6% of all cases or 11.6% of the revisions). There were no differences in all-cause revisions or revision for deep infection between the surgical helmet systems and conventional gowns ($p = 0.893$ and $p = 0.911$, respectively).

Conclusion

We found no evidence that wearing a surgical helmet system reduces the incidence of periprosthetic joint infection in any kind of primary shoulder arthroplasty. We acknowledge the limitations of this registry study and accept that there may be other benefits in terms of personal protection, comfort, or visibility. However, given their financial and ecological footprint, they should be used judiciously in shoulder surgery.

Take home message

- There is currently insufficient evidence to recommend the routine use of surgical helmet systems (‘space suits’) in primary shoulder arthroplasty as a means of reducing deep infection.

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Introduction

The role of body exhaust systems (BES), now known as surgical helmet systems (SHS), or colloquially, 'space suits', in the reduction of periprosthetic joint infections (PJI) is controversial.

Sir John Charnley pioneered BES as part of his strategy to reduce contamination in the operating theatre and they are commonly used in upper and lower limb joint arthroplasty today.[1] Modern SHS use a combination of a loose-fitting hood and an impermeable 'toga' to reduce bacterial shedding from the surgeon onto the surgical field and thus, theoretically, reduce the incidence of PJI.[2]

Conflicting evidence exists, however, regarding their efficacy. Some registry data suggest that modern SHS may reduce rates of infections or revision in over 19,000 total knee arthroplasties (TKAs).[3] On the contrary, in an earlier registry study of over 65,000 knees, SHS did not reduce the risk of deep infections,[4] a finding which is also supported by a systematic review and meta-analysis of nearly 4,000 patients.[5]

In some experimental studies, SHS are paradoxically hypothesized to be worse,[6-8] possibly due to contamination of the surgical field by the exhaust, although the variations in make and model of the suit may also be a contributing factor,[9] as may the donning technique.[10] To date, no large-scale studies have been conducted regarding their use in shoulder arthroplasty. We set out to investigate if the use of SHS was associated with reduced PJI in shoulder arthroplasty. We used data submitted to the New Zealand Joint Registry over a 20-year period. Our null hypothesis was that wearing a SHS would not reduce PJI or revision for infection following primary shoulder arthroplasty.

Methods

The New Zealand Joint Registry was established in 1999; submission of every arthroplasty performed in New Zealand is now a compulsory requirement for annual accreditation with the New Zealand Orthopaedic Association. Among other things, the registry records whether or not the surgical team wore conventional gowns or SHS. It also records patient factors including age, BMI, sex, and American Society of Anesthesiologists (ASA) grade,[11] as well as whether the operation took place in a laminar flow operating theatre. In revision cases, the primary indication for surgery is recorded (e.g. loosening, infection, malposition). Reports are published annually and are publicly available on the registry website.[12]

Implant survival is measured by revisions per 100 component years (as defined by time from surgery to either revision or death), so one revision per 100 component years = 1% revision at one year or 10% at ten years. The advantage of this system is that it allows comparison between components irrespective of how long ago they were implanted.

All primary shoulder arthroplasties (hemiarthroplasty [HA], anatomical total shoulder arthroplasty [aTSA], or reverse total shoulder arthroplasty [rTSA]) ever recorded on the New Zealand Joint Registry (i.e. from January 2000 to December 2023) were eligible for this study. We identified all joint arthroplasties that resulted in a revision procedure for infection; rate of infection was recorded as a percentage of all shoulder joint arthroplasties undertaken during the study period. Patient demographic data are shown in Table I.

Statistical analysis

The revision rates were summarized as the revision rates per 100 component years and compared using Cox proportional hazards regression (HR). The presenting features were compared between the groups using a chi-squared test or one-way analysis of variance (ANOVA) as appropriate to the variable types. A two-tailed $p < 0.05$ was considered statistically significant. Our study had approximately 80% power to detect a doubling (or worse) in revision rates between groups. Analyses were conducted using SPSS version 28.0 (IBM, USA).

Results

There were 16,045 primary shoulder arthroplasties registered on the New Zealand Joint Registry during the study period, which recorded information concerning the gowns used. A total of 9,693 patients (60%) were female; 56% of implants (n = 8,967) were reverse geometry TSAs. Table II.

Indications for surgery are shown in Table III. More than one indication can be cited, although the two commonest indications were osteoarthritis (18.7%) and rheumatoid arthritis (18.3%). Rotator cuff tears or massive rotator cuff tears were cited in 26% of cases (n = 4,188).

Overall, 37.4% of operations (n = 6,007) took place in laminar flow theatres; 2,728 operations (17%) took place with the staff wearing a SHS. There were 842 revisions (5% of cases) with just 98 for deep infection (0.6% in total or 11.6% of the revisions). Of 13,316 procedures that took place in conventional gowns, 702 resulted in a revision (5.27%), compared to 140 of 2,729 (5.13%) which used a SHS. Of the procedures in conventional gowns, 81 (0.6%) resulted in a revision for deep infection compared to 17 (0.6%) of those conducted using SHSs. There were no statistically significant differences in all-cause revisions or revision for deep infection between the SHS and conventional gowns respectively(HR = 0.99, 95% CI 0.82 to 1.18, p = 0.893) and (HR = 1.03, 95% CI 0.61 to 1.74, p = 0.911).

There was a statistically significant difference in procedure time between SHS and conventional gowns (115.6 mins vs 113.5 mins, p = 0.009, one-way ANOVA); however, this difference of approximately two minutes is unlikely to be clinically significant, and does not necessarily account for the additional time taken for gowning prior to knife to skin.

Discussion

We did not find any evidence from the New Zealand Joint Registry that wearing a SHS reduces the incidence of PJI in any kind of primary shoulder arthroplasty. To our knowledge, this is the largest ever study of its kind on this topic.

In keeping with other observations the number of TSAs is increasing, as is the ratio of reverse geometry TSAs compared to anatomical TSAs.[13] Mercifully, our study found that revisions for deep infections are rare (0.6%).

Other benefits of SHSs were considered to be outside the scope of this paper. Of late, focus has turned increasingly towards their role in safeguarding the surgeon from exposure to fluids or aerosols coming from the patient. Interestingly, the leading manufacturers currently recommend SHSs as personal protective equipment (PPE) and no longer include claims about infection prevention in their marketing.[14,15] There may

Table I. Patient characteristics.

Characteristic	Conventional, n (%)	SHS, n (%)	p-value*
Sex			0.656†
Female	8,034 (82.90)	1,659 (17.10)	
Male	5,282 (83.20)	1,070 (16.80)	
Age, yrs			< 0.001‡
< 55	858 (87.80)	119 (12.20)	
55 to 64	2,515 (85.00)	444 (15.00)	
65 to 74	5,161 (82.90)	1,065 (17.10)	
≥ 75	4,782 (81.30)	1,101 (18.70)	
ASA grade			< 0.001†
1	1,000 (86.50)	156 (13.50)	
2	6,808 (81.70)	1,526 (18.30)	
3	4,076 (81.20)	944 (18.80)	
4	123 (82.00)	27 (18.00)	
BMI, kg/m²			0.898‡
< 19	52 (85.20)	9 (14.80)	
19 to 24	1,121 (86.90)	169 (13.10)	
25 to 29	2,217 (86.00)	362 (14.00)	
30 to 39	2,420 (85.80)	402 (14.20)	
40+	437 (85.70)	73 (14.30)	

*Directly comparing whether a variable was associated with higher or lower use of surgical helmet system.
†Chi-squared test.
‡One-way analysis of variance.
ASA, American Society of Anesthesiologists; SHS, surgical helmet system.

Table II. Implant types used. In 13 cases (0.08%), the implant type was not recorded.

Implant type	Conventional, n (%)	SHS, n (%)
Hemiarthroplasty	2,018 (88.5)	261 (11.5)
rTSA	7,350 (82.0)	1,617 (18.0)
aTSA	3,936 (82.2)	850 (17.8)

aTSA, anatomical total shoulder arthroplasty; rTSA, reverse geometry total shoulder arthroplasty; SHS, surgical helmet system.

be other, more subjective indications such as surgeon comfort or visibility which may play a role in personal decision-making.

SHS also have drawbacks. Not only is there the purchase cost but there are ongoing financial and environmental costs associated with maintenance and consumables, which are frequently incinerated. The headsets themselves are frequently colonized by pathogens, such as *Cutibacterium acnes* and *Staphylococcus epidermidis* (although the significance of this is unknown).[16]

Table III. Indications for surgery.

Indication for surgery	Conventional, n (%)	SHS, n (%)	p-value†
Osteoarthritis	6,747 (81.30)	1,550 (18.70)	< 0.001
Rheumatoid arthritis	748 (81.70)	167 (18.30)	0.303
Other inflammatory condition	146 (83.90)	28 (16.10)	0.746
Rotator cuff tear	3,227 (83.80)	623 (16.20)	0.117
Massive rotator cuff tear	303 (89.60)	35 (10.40)	< 0.001
Acute fracture	1,255 (85.50)	213 (14.50)	0.008
Old trauma	763 (84.20)	143 (15.80)	0.312
Avascular necrosis	364 (84.70)	66 (15.30)	0.353
Dislocation	226 (84.60)	41 (15.40)	0.469
Tumour	11 (91.70)	1 (8.30)	0.424
Other	587 (86.70)	90 (13.30)	0.009

*Directly comparing whether a variable was associated with higher or lower use of surgical helmet system.
†Chi-squared test.

In recent years, there has been an insurgence of interest in advanced navigation techniques or augmented reality in shoulder arthroplasty surgery.[17,18] Such systems often require the surgical team to wear a headset intraoperatively which may preclude the use of space suits.

Our study has some limitations. Level 1 evidence for infection prevention in shoulder arthroplasty is difficult to gather due to the low numbers of surgeries worldwide and low rate of PJI (just 0.6% of cases in this study). Registry studies represent a reasonable alternative, but they are not without their problems. Most presciently, although the New Zealand Joint Registry records basic demographic data, including age, sex, BMI, and ASA grade, this is not an exhaustive list of comorbidities. It is conceivable that surgeons who consider individual patients to be high-risk (e.g. those with diabetes, immunosuppression, and/or previous infections) selectively choose to wear a SHS as a countermeasure, introducing a possible source of selection bias.

Additionally, it is possible that some revision arthroplasties were not recorded, or that infection was not cited as an indication for revision at the time (even if this transpired to be the case subsequently). Furthermore, we were unable to draw any conclusions about the brand of SHS garments used, or the donning techniques of the individual users.

In conclusion there is currently insufficient evidence to recommend the routine use of SHS in primary shoulder arthroplasty as a means of reducing PJI. Given their cost and environmental footprint, they should be used judiciously.

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Data sharing

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Ethical review statement

The New Zealand Joint Registry has national ethical approval. Patients undergoing joint arthroplasty provide consent to collection and use of their data.

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